UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

EDWARD KO and DERSON O. JOLTEUS, Individually and on behalf of all others similarly situated, of all others similarly situated, Plaintiffs, v. NANO-X IMAGING LTD., RAN POLIAKINE, and ITZHAK MAAYAN, Defendants.	Case No.: 1:20-cv-04355-WFK-MMH Hon. Judge Kuntz Hon. Magistrate Judge Henry **CONSOLIDATED CLASS ACTION COMPLAINT** **DEMAND FOR JURY TRIAL**

AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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Lead Plaintiffs Edward Ko and Derson O. Jolteus ("Plaintiffs"), individually and on behalf of all other persons similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' Consolidated Class Action Complaint against Defendants, allege in this Amended Class Action Complaint for Violation of the Federal Securities Laws (the "Complaint") the following upon knowledge with respect to their own acts, and upon facts obtained through an investigation conducted by their counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Nano X Imaging Ltd. ("Nano-X") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of the defendants' public documents, conference calls and press releases; and (c) information readily obtainable on the Internet, including media and analyst reports.

Plaintiffs believe that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of purchasers of Nano-X securities between August 21, 2020 and September 15, 2020, inclusive (the "Class Period"), seeking to recover compensable damages caused by Defendants' violations of Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5.

2. Nano-X is an Israeli company that purportedly develops and produces X-ray source technology for the medical imagining industry. Its promise to disrupt the medical imaging industry generated a lot of buzz surrounding its IPO on Nasdaq in August 2020.

3. One factor that generated buzz was Nano-X's claims to have identified and developed a novel X-ray source, based on a digital microelectromechanical system semiconductor

cathode that could achieve the same functionalities as legacy X-ray analog cathodes. This digital X-ray source is claimed to be the basis of the core technology in the imaging system that the company is developing, which otherwise would be equivalent existing technology. Nano-X represented that it would be able to quickly obtain regulatory approval for its technology from the Food & Drug Administration and other national regulators worldwide.

4. A second factor that generated buzz amongst investors is the business model that would bundle cloud-based services—the Nanox.Cloud—around the core imaging device—the Nanox.ARC X-ray machine—and software—the Nanox.Cloud. Nano-X calls this Medical Screening as a Service ("MSaaS"). Using this combination, Nano-X is to provide a medical image repository, radiologist matching, image distribution for example to remote clinicians, online and offline diagnostics review and annotation, AI-based automated diagnostics, billing, and reporting.

5. Notwithstanding going public at a pre-product stage, Defendants' Registration Statement touted a projected $163.8 million in annual revenue from these MSaaS agreements with distributers across four continents. Nano-X did not have prototype of its commercial product to demonstrate, let alone regulatory approval, yet these distributors purportedly committed to provide millions of dollars in services annually, backed by a letter of credit.

6. Former CEO, Defendant Ran Poliakine, also generated buzz for Nano-X. Prior to and during the Class Period, Defendant Poliakine made bold claims about Nano-X's technology and its customers. Before the IPO, Defendant Poliakine stated that the Nano-X System would eliminate the need to use different imaging machines for different procedures, such as mammography, CT, fluoroscopy, and angiography. He compared using the Nano-X System for different types of medical imaging to using an iPhone to listen to music, take pictures, and make phone calls.

7. Poliakine promoted the Nanox.ARC's regulatory prospects as well as the commercial viability of the Nanox System. He told investors that the distributors were "committed customers" and "appropriate partners" with experience in the medical imaging industry. He also told investors that it was a "reasonable assumption" that the Nanox.ARC would get regulatory approval in the near-term and it would soon be "ready to go prime time."

8. As a result of the buzz that Defendants generated, the gross proceeds of its IPO were approximately $190 million. Its stock price shot up from its IPO price of $18/share to a Class Period high of $64.19/share on September 11, 2020. Nano-X's market cap was $1.8 billion by early September 2020.

9. On September 15, 2020, analyst firm Citron Research, which has exposed several fraudulent companies published an exposé, titled "Nano-X Imaging (NNOX) A Complete Farce on the Market – Theranos 2.0" (the "Citron Report") that revealed, among other things, "NNOX's commercial agreements may sound nice on the surface, but these appear to be no more than fake customers." The Citron Report also revealed that Nano-X mislead investors about their technology by mischaracterizing their FDA application. On this news, Nano-X's share price fell $12.41 per share, or more than 25%, over the next two trading days to close at $36.80 per share on September 16, 2020.

10. The truth was that there was no plausible pathway for Nano-X to carry out its MSaaS business model. Expectations of rapid approval from the FDA—that it was a "reasonable assumption" that the Nanox.ARC would get regulatory approval in the near-term and it would soon be "ready to go prime time"—were false given known deficiencies with Nano-X's submissions. Statements about Nano-X's distributors, including that they were "appropriate partners, partners that are already in the field, they know their own local market, and they are

capable financially and otherwise to carry out our business model" were false given that they lacked experience in the industry making them ill-suited to execute the MSaaS business plan, even if the FDA approved the Nanox.ARC.

11. Several post-class period disclosures also shed light on the Defendants' fraud and the falsity of their statements. Notably, on September 22, 2020, analyst firm Muddy Waters Research, published its own lengthy exposé, titled "Nanox: Star Trek, Theranos, and Nikola" (the "Muddy Waters Report"). The Muddy Waters Report echoed the conclusions of the Citron Report and included interviews with radiologists, a former FDA official, Nano-X's partners, a Nano-X Advisory Board Member, and a former Nano-X employee. The Muddy Waters Report identified serious deficiencies with the distributers Nano-X listed in the prospectus, noting that they lacked industry expertise, were unable to obtain the letter of credit in the amount stated, were incapable of providing stated service levels, and the agreements provided significant contingencies for the distributers. The radiologists interviewed by Muddy Waters Research voiced a profound lack of belief in Nano-X's claims and technological validity. Ultimately, the Muddy Waters Report concluded, "that NNOX has no real product to sell other than its stock."

12. On or about May 5, 2021, the FDA published its approval letter for a device that the Defendants described as the single-source version of the Nanox.ARC. It was revealed that Defendants' technology could not enable early detection of cancer or cardiovascular disease, let alone perform a simple chest X-ray. The indicated use for the single-source device is *only* for X-ray examinations of the hands, wrists, and fingers. It is explicitly not intended for general radiographic X-ray examinations or diagnostic applications including mammographic, angiographic, and fluoroscopic procedures. It is also not an "arc" based device, but rather a mobile X-ray unit that is objectively inferior to similar machines already on the market.

13. Since September 2020, Nano-X has received no revenue from any of its distributors or implement any of its purported MSaaS strategy. Two years after the end of the Class Period, it has just applied for FDA approval to market its Nanox.ARC.

14. When the truth about Nano-X's regulatory prospects and distributors emerged, the stock price declined as the market discovered the true value of Nano-X. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Nano-X securities, Plaintiffs and other Class members suffered significant losses and damages.

II. JURISDICTION AND VENUE

15. The federal law claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j, 78t] and Rule 10b-5 promulgated thereunder by the SEC [17 C.F.R. § 240.10b-5].

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act [15 U.S.C. §78aa].

17. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

18. Venue is proper in this District pursuant to Section 27 of the Exchange Act [15 U.S.C. §78aa] and 28 U.S.C. § 1391(b) because certain of the acts alleged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in this District.

III. PARTIES

19. Pursuant to this Court's Order of August 30, 2022 (ECF No. 51) Edward Ko and Derson O. Jolteus were appointed Lead Plaintiffs. Plaintiffs purchased Nano-X securities within

the Class Period and, as a result, were damaged thereby. Plaintiffs' certifications evidencing their transactions are incorporated by reference herein from their motion for appointment of lead plaintiffs. *see* ECF Nos. 12, 31, and 35.

20. Defendant Nano-X purportedly develops and produces X-ray source technology for the medical imaging industry. Nano-X is incorporated in Israel with its principal executive offices located at Communications Center, Neve Ilan, Israel, 9085000. Nano-X's securities are traded on NASDAQ under the ticker symbol "NNOX."

21. On July 30, 2020, Nano-X filed a Registration Statement on Form F-1 with the SEC. Following subsequent amendments, the Registration Statement was declared effective on August 20, 2020. Defendants Poliakine and Maayan signed the Registration Statement. On August 25, 2020, Nano-X filed its final prospectus, which incorporated andformed part of the final Registration Statement, with the SEC on Form 424B4. (collectively referred to as the "Registration Statement").

22. Nano-X securities began trading on NASDAQ on August 21, 2020.

23. Defendant Ran Poliakine ("Poliakine") has served as Nano-X's Chief Executive Officer ("CEO) and a Director from Nano-X's formation and throughout the Class Period. On August 10, 2021, Nano-X announced with the release of its second quarter-financial results that Defendant Poliakine would relinquish his role as CEO in January 2022 but continue his role as Executive Chairman. Defendant Poliakine signed the Registration Statement, which contained various alleged material misstatements and omissions. Defendant Poliakine also made various alleged material misstatements in investor presentations.

24. Defendant Izhak Maayan ("Maayan") has served as Nano-X's Chief Financial Officer ("CFO") throughout from November 2019 throughout the Class Period. On August 10, 2021, Nano-X announced with the release of its second quarter-financial results that Defendant

Maayan would resign as CFO at the end of September 2021. Defendant Maayan signed the Registration Statement, which contained various alleged material misstatements and omissions.

25. Because of Poliakine and Maayan's (collectively "Individual Defendants") positions within Nano-X, they had access to undisclosed information about Nano-X's business, operations, operational trends, financial statements, markets and present and future business prospects via access to internal corporate documents (including Nano-X's operating plans, budgets and forecasts and reports of actual operations and performance), conversations and connections with other corporate officers and employees, attendance at management and Board meetings and committees thereof and via reports and other information provided to them in connection therewith.

26. As officers of a publicly-held company whose securities were, and are, registered with the SEC pursuant to the federal securities laws of the U.S., Poliakine and Maayan each had a duty to disseminate prompt, accurate and truthful information with respect to Nano-X's financial condition and performance, growth, operations, financial statements, business, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of Nano-X's publicly-traded securities would be based upon truthful and accurate information. Poliakine and Maayan were each provided with copies of Nano-X's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these individuals knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading.

27. Poliakine and Maayan participated in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Nano-X securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived

the investing public regarding Nano-X's business, operations, management and the intrinsic value of its securities and (ii) caused Plaintiffs and other shareholders to purchase Nano-X securities at artificially inflated prices.

28. Nano-X is liable for the acts of Poliakine, Maayan, and its employees under the doctrine of *respondeat superior* and common law agency principles as all the wrongful act complained of herein were carried out within the scope of their employment with authorization.

29. The scienter of Poliakine, Mayaan, and other employees and agents of Nano-X are similarly imputed to Nano-X under *respondeat superior* and common law agency principles.

IV. SUBSTANTIVE ALLEGATIONS

A. Company Background

30. Incorporated under the laws of the State of Israel under the name "NANO-X IMAGING LTD" on December 20, 2018, Nano-X commenced its operations on September 3, 2019. Substantially all Nano-X's assets were acquired or assigned from its predecessor company, Nanox Imaging PLC, a Gibraltar public company, which, upon information and belief, Defendant Poliakine founded in or about 2011. The assets included technology that was apparently originally developed by Sony for television screens and monitors, offering a novel way of lighting screen pixels compared to traditional cathode-ray tubes that were based on a one-source electron gun beam.

31. After acquiring the technology, Nano-X and its predecessor company purportedly spent over eight years developing a digital X-ray source for the medical imaging industry to be produced on a commercial scale. By January 2020, Nano-X had raised a total of $55 million in funding to support the development of the Nano-X System from companies such as Fujifilm, SK Telecom, and Foxconn. However, per Defendants' draft registration statement, dated February 7, 2020, at that point they had not produced a working protype of the Nanox.ARC or developed a

beta version of the Nanox.Cloud. Prior to the IPO, it was reported that the Nano-X had raised another $110 million in funding. As of June 30, 2020, Nano-X had 21 employees based in Israel and six employees based in Japan.

B. Nano-X's IPO

32. On July 30, 2020, Nano-X filed a Registration Statement on Form F-1 with the SEC. On August 14, 2020, the Defendants filed Amendment No. 1 to Form F-1 Registration Statement. On August 20, 2020, the Defendants filed Amendment No. 2 to Form F-1 Registration Statement. (together, the July 30, August 14 and August 20, 2020 Registration Statements, are referred to, as the "IPO Registration Statement"). The IPO Registration Statement was declared effective on August 20, 2020.

33. The Individual Defendants signed the IPO Registration Statement.

34. On August 24, 2020, Nano-X filed its final prospectus with the SEC on Form 424B4, which incorporated and formed part of the final IPO Registration Statement.

35. The IPO closed on August 25, 2020. In the IPO, the Nano-X sold "10,555,556 ordinary shares" at "$18 per share for gross proceeds of approximately $190 million."

C. The Nano-X System

36. Defendants described their technology in their Registration Statement as follows:

> We have developed a prototype of the Nanox.ARC, a medical device that integrates our proprietary and novel X-ray source. Subject to receiving regulatory clearance, the first version of the Nanox.ARC that we expect to introduce to the market is expected to be a 3D tomosynthesis imaging system that produces a 3D reconstruction of the scanned human body part, as illustrated in the image below. The Nanox.ARC, using our X-ray source, is being designed to produce partial and full-body scans, with remote operation capability, and to have a full kVp/mA energy throughout range as per industry standards, multi-spectral imaging range, as well as quiet operation, cloud connectivity and standard compliance

> safety mechanisms. It is being designed for easy setup and operation with multiple stationary X-ray tubes arranged around the patient.
>
> In addition to the Nanox.ARC, we have developed a prototype of the Nanox.CLOUD, a companion cloud software that will allow for the delivery of medical screening as a service. With the Nanox.CLOUD, we anticipate that the high-cost components of existing medical imaging systems, such as analytics and computing software that are traditionally installed via multiple licenses on-premise and on a per-system basis, will become centralized through the cloud. We believe this will significantly reduce on-going software and IT licensing costs and enable a wide range of functionalities, such as per-body-part vertical analysis, multiple AI diagnostics and remote support. The Nanox.CLOUD is also expected to be able to provide an end-to-end medical imaging service, including services such as image repository, radiologist matching, online and offline diagnostics review and annotation, connectivity to medical imaging AI systems and billing and reporting.

37. Defendants describe the Nanox.ARC system as "being designed to produce partial and full-body scans, with remote operation capability, and to have a full kVp/mA energy throughout range as per industry standards, with multiple stationary X-ray tubes arranged around the patient." Regarding the X-ray tubes, the F1 filing states that "Our X-ray source is based on a novel digital microelectromechanical system ("MEMs") semiconductor cathode" and that "[t]his novel digital X-ray source is the basis of core technology in the Nanox.ARC". The Registration Statement further states that "the first version of the Nanox.ARC that we expect to introduce to the market will be a three-dimensional ("3D") tomosynthesis imaging system." Therefore, Nano-X's plan is to enter the market with a 3D tomosynthesis imaging system with multiple stationary MEMS-based X-ray tubes arranged around the patient.

38. While tomosynthesis is a newer 3D imaging technique than computerized tomography ("CT"), tomosynthesis devices are already available in the market. For example, General Electric makes the VolumeRad, an advance medical imaging device that provides digital

tomosynthesis. Despite their use of a traditional X-ray source, currently available tomosynthesis devices are nevertheless cheaper, smaller, and in certain cases provide improved imaging capabilities compared to legacy CT scanner. Nanox's Registration Statement as well as its website consistently notes that the cost of the Nanox.ARC is expected to be substantially lower than legacy CT devices. However, given that the cost of tomosynthesis chest examination can be as low as 15% of the cost of a chest CT examination, their comparison is inapposite. An accurate comparison would be between the cost of the Nano.ARC device with existing tomosynthesis devices.

39. Defendants claim that Nano-X's digital X-ray source generates X-ray radiation that is measurably identical in all key metrics to the X-ray radiation generated by existing analog X-ray sources, but without creating the high temperature that results from the filament used in the analog X-ray tube, thereby eliminating the need for the costly cooling equipment. They further state that Nano-X's X-ray source is designed to enable the Nanox.ARC to have multiple stationary tubes arranged around the patient, which allows for a more simplified structure, as opposed to requiring the heavy, complex, high-precision rotating mechanisms used in legacy CT devices. The Nanox.ARC itself consists of a table and a moving arch that can hold multiple X-ray tubes.

40. At the time of the IPO, the Nano-X's patent portfolio consisted of eleven applications, some of which matured into patents. Nine of those applications are directed to aspects of the MEMS-based X-ray source or control circuits for the X-ray source. Two of the filings are focused on using multiple stationary x-ray sources for tomosynthesis.

41. Their most recent Patent Cooperation Treaty ("PCT") publication prior to the IPO, #WO2020158644A1, expressly distinguished between a conventional tomosynthesis device using a single hot cathode X-ray tube mounted on a rotating mechanism (excerpted Fig. 1A) and Nano-

X's new tomosynthesis device using a plurality of small cold cathode X-ray sources arranged in an arc (Fig. 2B), stating:

> When a small cold cathode X-ray tube is used as an X-ray source for tomosynthesis imaging, a dozen to several tens of cold cathode X-ray tubes are placed on the orbit of the hot cathode X-ray tube in the conventional tomosynthesis device. By arranging the individual images a number of times and sequentially blinking these to irradiate X-rays, the same imaging as the method described in FIGS. 1A to 1C [the conventional method] can be performed.

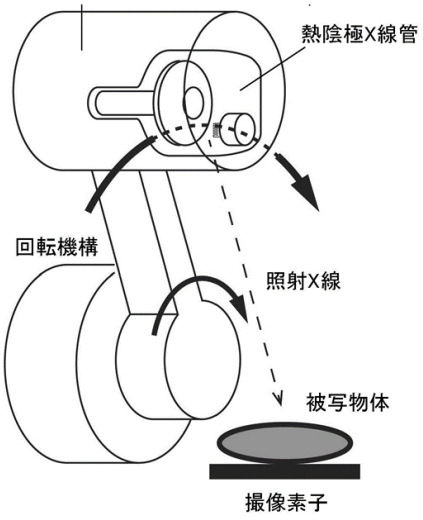


Fig. 1A

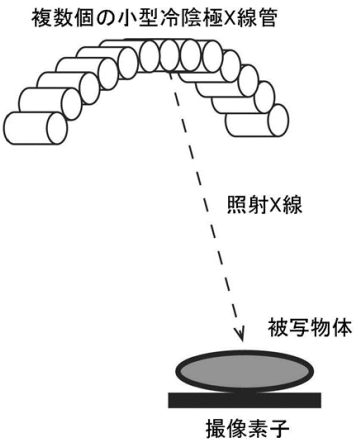
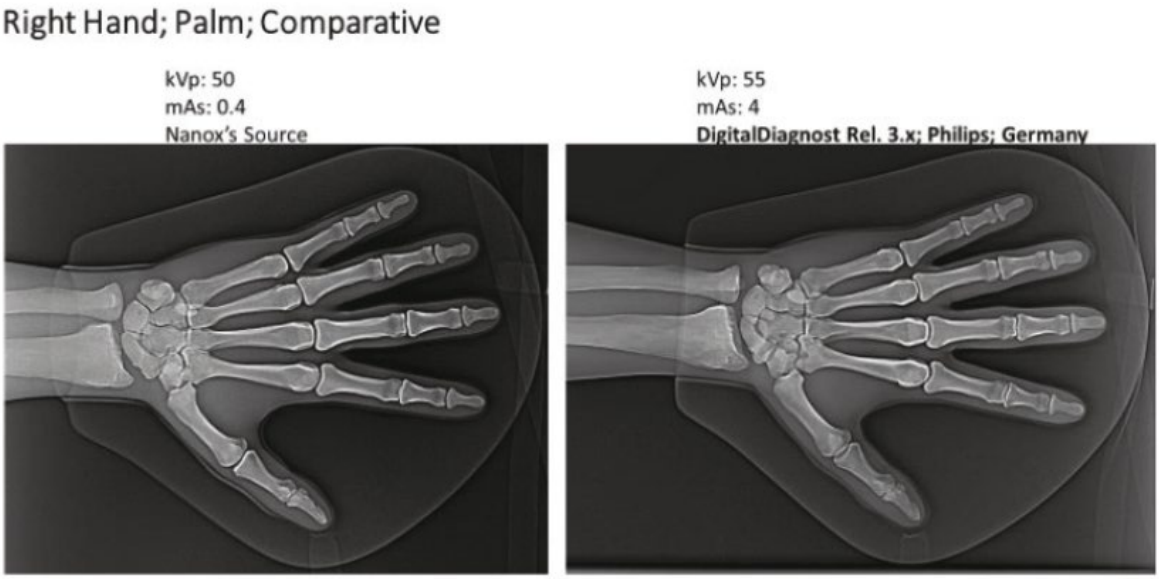


Fig. 2B

42. The WO2020158644A1 publication notably lacked experimental results and a sample 3D tomosynthesis image. Although experimental results or sample images are not required for patent approval, it shows that when Nano-X filed the application on January 27, 2020, it did not have a functioning prototype and could not produce a 3D tomosynthesis image.

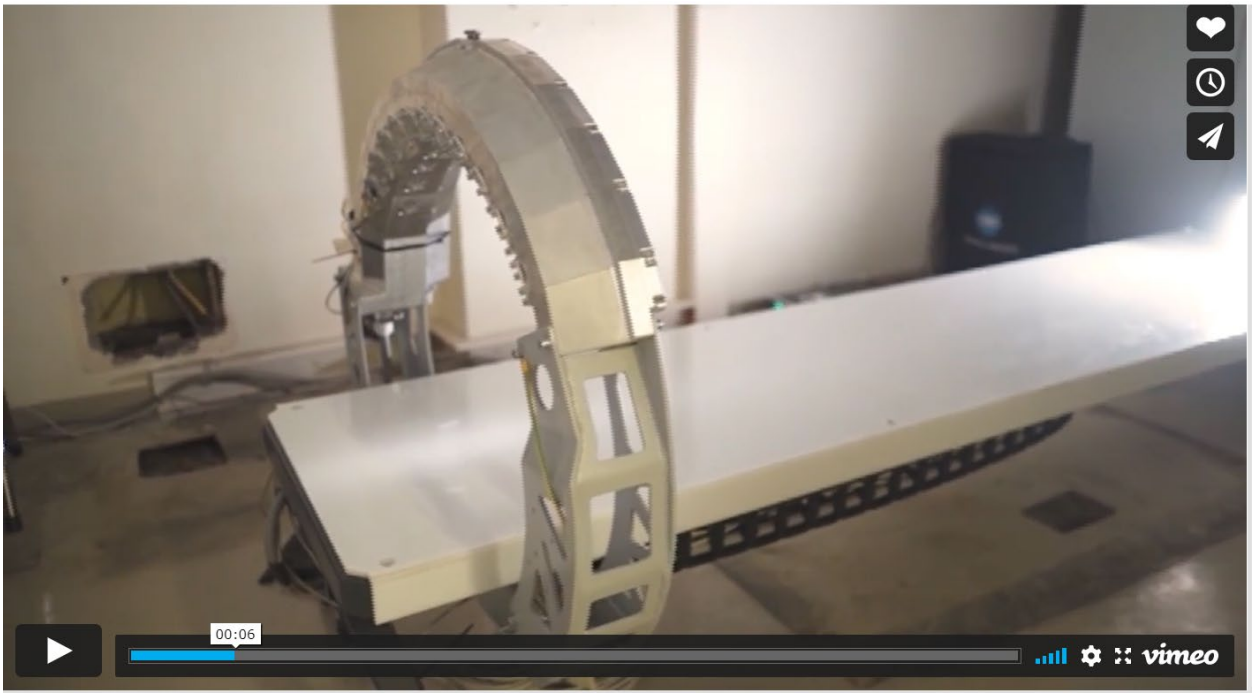
43. Between the January 2020 application and the IPO, Nano-X still did not have a function tomosynthesis prototype. The July 2020 F1 filing included only standard 2D X-ray images. They were acknowledged by Nano-X to have been taken with a single X-ray source: "We have generated the images below with the Nanox.ARC using a single X-ray tube on an imaging phantom."

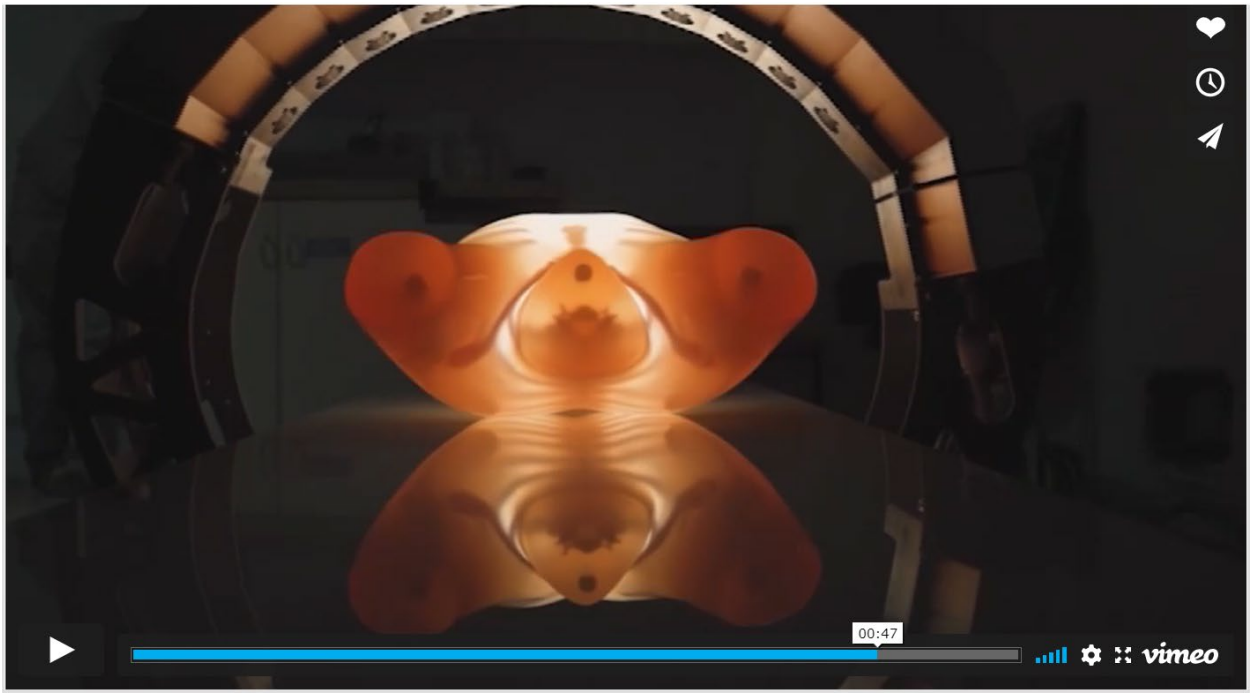


44. The Registration Statement acknowledges that, as of the July 30, 2020 filing, Nano-X had filed a 501(k) application for the single-source version of the Nanox.ARC only and has not yet filed a 510(k) application for the multi-source version.

45. The single-source version of the Nanox.ARC only uses one X-ray tube. Defendants stated that once the single-source version is approved, Nano-X planned to submit an additional 510(k) application under the Third-Party Review Program with respect to the multiple-source Nanox.ARC which will be their commercial imaging system. They expected to submit this application in the fourth quarter of 2020.

46. Nano-X also published demonstration videos on their website and their Vimeo page, which alleged showcased the Nanox.ARC prototype. The following images were from one of their videos each show a movable metal arc with about a dozen indentations on the interior surface that appear to be where the MEMS-based X-ray sources are housed. The device therefore has the appearance of a multi-source version and resembles above-excerpted Fig. 2B of PCT publication WO2020158644A1.





47. However, as discussed *infra* Section VII A, it is clear that the device only captured a 2D image. The images Nano-X revealed, were criticized by the radiologists in the Muddy Waters

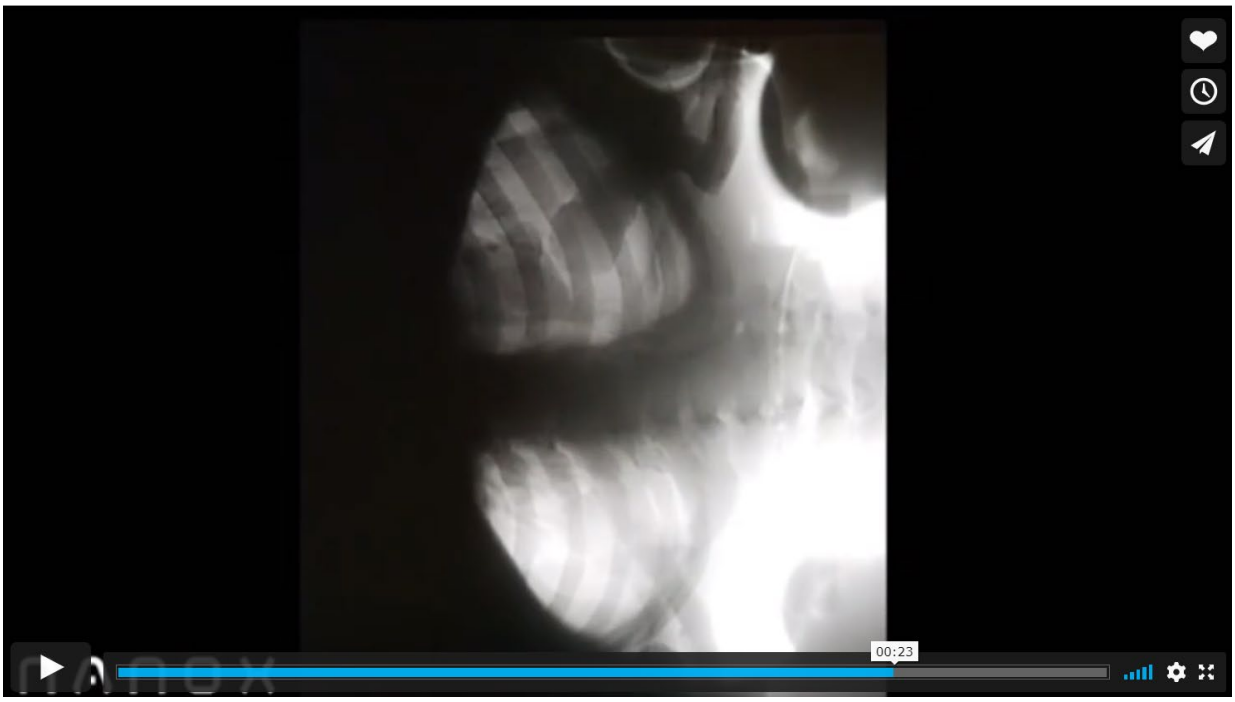
report as entirely underwhelming, on par with antiquated X-ray technology already available in cheap machines:

> "The easiest thing in the world to do is take an X-ray. People make very cheap X-ray machines. That's the first thing is, all you're seeing is you're taking an X-rayof a foot. That's the easiest thing in the world. Remember, Roentgen took an X-ray of a hand in 1895. That was the first image he ever made, his wife's hand with a ring on. To make an X-ray of a foot, and it looked nothing special, but to say you can take an X-ray of a foot is not exactly stellar technology."
>
> "They're making this thing seem like it's a CT scanner that will do what a CT does. It might be able to do what a planar X-ray does. In which case it's an interesting but very expensive version of a machine that can do an X-ray. On the other hand, if it does what a CT does it could change the world which is why these people are spending orinvesting this money but there's no evidence it's ever going to be able to do that."

48. Nano-X published a video showing a test dummy, known as a phantom, in an unidentified room being passed over by a prototype of the Nanox.ARC. The video then cuts to full-screen shots of a black-and- white, rotating chest image on the left side of the screen and a stationary image of a chest on the right. Radiologists that Muddy Waters spoke with opined that the imaging footage is fake. Three radiologists noted that this position is never how chest CT scans are done, as the arms get in the way of the chest image, suggesting that knowledge of radiology or radiography is lacking at Nano-X. One radiologist stated that there appeared to be something wrong with the way the ARC acquired the image in the top right once the machine advanced past the mid-torso: "It's just one big blur." Regardless, the video then switches to two shots that take up the entire screen.

49. After the Muddy Water's Report, the video discussed by the radiologists was removed and replaced with a shorter video on the Defendants' Vimeo page. On October 1, 2020, Muddy Waters published a video demonstrated that the originally posted video included a 3D

image, which was then edited. Therefore, the prototype shown in the videos published by Nano-X was most likely a single-source device that was not yet equipped to perform a 3D tomosynthetic scan. The following images were from one the videos, which clearly demonstrate that the machine could only capture a 2D image:



50. In a chest imaging demonstration video, discussed *infra*-Section VII A, Nano-X claimed to show an example of the Nanox.ARC's 3D tomography capability with a rotating view of a phantom's chest. However, the rotating image clearly had its arms up, as opposed to crossing its chest as displayed in the video, and the radiologists Muddy Waters interviewed doubted that the images came from the Nanox.ARC. The new video only contained the right-hand X-ray, which two radiologists called unreadable. The original video also showed panning shots of Hadassah hospital and walkthrough footage of its hallways, stating that it was recorded in December 2019.

51. Muddy Waters Research interviewed several radiologists who wondered why there were few images that Nano-X made public outside of the above referenced rudimentary X-rays. They emphasized that this runs in stark contrast to industry practice.

52. Muddy Waters Research also interviewed a member of NNOX's Advisory Board who admitted to not having seen 3D images:

> No, I have not seen a live demonstration… I have not seen a working device or any pictures or images from or computerized tomography pictures of this, or images with this device yet. I don't think that's something that is done yet. As far as I know, no one has gotten scanned by this device yet.

53. As discussed in the following section, the 510(k) application for the single-source version of the Nanox.ARC was for a device that was far less functional than those already available. Its limited abilities contradict the Defendants' claims about the multiple-source Nanox.ARC.

D. <u>Regulatory Approval</u>

54. Nano-X must obtain regulatory approval from each country where it seeks to deploy its devices. To be used in the countries listed in the Registration Statement, Nano-X needs the approval of the European Medicines Agency in the form of Conformité Européenne ("CE")

mark and the approval of regulatory authorities in Australia, Brazil, Russia, Singapore, South Africa, Taiwan, and New Zealand. In their September 2020 Investor Presentation, Defendants stated that most of the countries in the world would accept either the FDA approval or CE mark as a reference for local clearance while some countries will require separate submissions. They did not further clarify the regulatory requirements or provide any information about applications for approval outside of the United States.

55. Defendants elected to take a multi-step approach to the regulatory clearance process in the United States. In January 2020, Nano-X submitted a 510(k) application for a single-source version of the Nanox.ARC to an accredited Review Organization, Accelerated Device Approval Services ("Accelerated Device"), under the FDA's Third-Party Review Program. Under this program, the FDA allows accredited organizations to review submissions for eligible devices to demonstrate that a device to be marketed in the U.S. is as safe and effective, or substantially equivalent, to a legally marketed device.

56. Applicants must compare their device to one or more similar legally marketed devices to support their substantial equivalence claims. The legally marketed device to which equivalence is drawn is also known as the predicate device. A device is substantially equivalent if, in comparison to a predicate device it has the same intended use and has the same technological characteristics as the predicate; or has the same intended use as the predicate and has different technological characteristics, does not raise different questions of safety and effectiveness, and the information submitted to the FDA demonstrates that the device is as safe and effective as the legally marketed device. Once satisfied with the application, the accredited organization submits it to the FDA, which makes the final determination about the submission.

57. By filing a 510(k) application as opposed to a *de novo* or Pre-Market Approval Submission, Defendants claimed that the single-source Nanox.ARC was equivalent to an FDA-approved X-ray imaging system by another market participant, and made no new claims as to the operation, image quality or functionality of the Nanox.ARC versus the predicate device. Defendants also stated that the application for the multiple-source Nanox.ARC, the commercial application, would be a 510(k) application and not a Pre-Market Approval Submission. Therefore, the commercial application would need to be equivalent to an FDA-approved X-ray imaging system.

58. Despite not applying for approval of the multiple-source Nanox.ARC, their commercial imaging system, Defendants presented the likelihood to investors that the FDA could clear this device for usage and that it could be deployed in the first half of 2021.

59. Defendants have also not applied for clearance to use the Nano-X System in any other country but stated in the same presentation that they expected to apply for a CE mark and that it would be also cleared in the first half of 2021.

60. In its registration statement, Nano-X described its multi-step regulatory process as follows:

> **"Secure regulatory clearance for our medical imaging system.** We expect to take a multi-step approach to the regulatory clearance process. As a first step, we submitted a 510(k) application for a single-source version of the Nanox.ARC to an accredited Review Organization under the Third-Party Review Program in January 2020. In response to the feedback, we received from the reviewer, we are conducting standard functional and safety tests to support the 510(k) application and expect to submit the results from these tests in the third quarter of 2020. The timeline was delayed due to the impact of COVID-19 on the external labs we work with to complete these tests. We will continue to optimize and develop further features of the Nanox.ARC, and plan to submit an additional 510(k) application under the Third-Party Review Program with

> respect to the multiple-source Nanox.ARC during the fourth quarter of 2020, which, if cleared, will be our commercial imaging system."

61. Defendants never explain why they felt it was necessary to take a multi-step approach to the regulatory clearance process or why it was necessary to obtain marketing approval for a device that they have no intention of commercializing. There was no requirement to obtain marketing clearance for the single-source Nanox.ARC before applying for approval of the multiple-source Nanox.ARC.

62. Defendants' characterization of the Accelerated Device's comments as mere "feedback" downplayed the gravity of the criticisms. In fact, the comments came in the form of a major deficiency letter received in March 2020. Muddy Waters Research interviewed a former FDA official for its report who explained that:

> "What a major deficiency letter means, they don't think this product is ready to launch. Yes, of course, because major deficiency letters are drafted in a way where something big is lacking. That means they are lacking in completely analytical validation or clinical validation as part of the study. Something is really lacking big time."

63. In a Form 6-K filed with the SEC on September 10, 2020, Nano-X announced that on September 3, 2020, it finally submitted a response to Accelerated Device's major deficiency letter, six months after it had been received in March 2020. Defendants claim that COVID-19 delayed their response to the major deficiency letter is similarly suspicious. Considering Nano-X's 510(k) application was only supported by bench testing, which evaluated the X-ray's mechanical performance, using a phantom device and not intensive clinical testing on animals or humans, claiming COVD-19 as an excuse for a six-month delay for what should have been a straightforward equivalency test is doubtful. If the bench testing was conducted in Israel, as Defendants suggest, where COVID-19 related lockdowns were first lifted in early May 2020, their excuse for this delay is unfounded.

64. Nano-X's September 3, 2020 response to the deficiency letter included additional data and other information to complete the application and to address certain deficiencies highlighted by the reviewer, including the results of certain performance tests. However, Nano-X's responses did not satisfy Accelerated Device's concerns. It did not submit the 510(k) application to the FDA until December 28, 2020, and even then, per Nano-X's January 30, 2021 Form 20-F, the FDA still requested additional information from Nano-X on January 30, 2021. The FDA required Nano-X to address certain deficiencies and provide additional support regarding the intended use of the Nanox.ARC and the comparability of the Nanox.ARC to the predicate device. Defendants submitted their response to these requests on March 1, 2021.

65. On or about May 5, 2021, the FDA published its partial clearance letter approving the single-source Nanox.ARC, called the "Nanox Cart X-ray System" (or the "Nanox Cart") along with Nano-X's March 1, 2021 submission file. The letter and the file revealed that the Nanox Cart is not, in fact, an arc shaped machine with a single X-ray tube, but rather a stationary mobile X-ray unit that cannot operate without being plugged into an electrical outlet and can only be used in a fixed position. The indicated use is for the Nanox Cart is for X-ray examinations of hands, wrists, and fingers only. It is explicitly not intended for "general radiographic X-ray examinations…or for mammographic, angiographic, interventional, or fluoroscopic applications." The predicate devices—what Defendants told the FDA its machine is substantially like—are mobile X-ray systems manufactured by GE and by Carestream Health Inc. Both of those devices are indicated for use in all general-purpose X-ray diagnostic procedures. The Nanox Cart is therefore not equivalent to existing FDA-cleared X-ray imaging systems.

66. Sixteen months after providing Accelerated Device with its first application, Nano-X obtained approval for a machine that is objectively inferior to similar devices already on the

market and far more limited and inferior to the device it described to the public and its investors. Contrary to representations that its device would consist of a moving arch with multiple X-ray tubes providing whole body scans capable of diagnosing cancer, Nano-X's product in 2021 consisted of just a single-source stationary X-ray cart to be used on wrists, hands, and fingers.

67. On June 17, 2021, the Nano-X finally submitted its 510(k) submission for its Nanox.ARC.

68. On August 19, 2021, Nano-X announced that it received a request for additional information from the FDA on August 12, 2021 and placed the application on hold pending a complete response to the FDA's list of deficiencies.

69. On January 12, 2022, Nano-X issued another press release stating that it filed a submission for "the second version" of the Nanox.ARC, which was "an improved and enhanced versions that was designed…to address certain deficiencies raised by FDA during their review." It informed investors that the June 2021 510(k) submission was withdrawn, and that they had filed a Q-Submission. The FDA's Q-Submission Program provides submitters an opportunity to have early collaboration and discussions about medical device submissions and is not a filing for marketing approval. The process is ongoing and on September 26, 2022, they submitted another 510(k) submission.

70. Nano-X still does not have clearance in any jurisdiction for the Nanox.ARC.

E. Nano-X's MSaaS Business Model and Nano-X's "Customers."

71. In the Draft Registration Statement, filed with the SEC on December 4, 2019, Defendants simply stated that: "[t]he Nanox System is designed to enable medical screening as a service ("MSaaS") to improve accessibility and affordability of early-detection services worldwide." After receiving a letter dated December 31, 2019 from the SEC, on January 14, 2020,

the Nano-X filed an amended Draft Registration Statement, which clarified that the MSaaS was a subscription model.

72. On February 11, 2020, Nano-X announced in a press release that it had entered its first MSaaS agreement with The Gateway Group, Ltd., the parent company of Intertrading Australia Ltd. ("Gateway").

73. Under the terms of a purported MSaaS agreement, Nano-X's customer is a distributor who is given a limited, non-transferable, exclusive, sublicensable right to access and operate the Nano-X System in a specific geographic region. The distributer must then deploy the Nano-X System to a medical services provider who will perform a minimum number of scans per year on a pay-per-scan basis and to pay a minimum annual fee. If the providers do not perform the required number of scans, the distributers will have to pay Nano-X through a standby letter of credit in the amount equal to the minimum annual fee in favor of Nano-X.

74. Nano-X filed another Draft Registration Statement on February 18, 2020. The February 18, 2020 Draft Registration Statement first mentioned Nano-X's customers:

> We entered into a Medical Screening as a Service Agreement (the "MSaaS Agreement"), dated February 11, 2020, with Intertrading Australia Ltd. ("Intertrading Australia"). Under the terms of the agreement, we grant Intertrading Australia a limited, non-transferable, exclusive, sub-licensable right to access and operate the Nanox System in Australia, New Zealand and Norway. We undertake to provide 1,000 Nanox Systems, subject to local regulatory approval and material compliance with acceptance test protocol. Intertrading Australia undertakes to deploy the systems to provide a minimum number of scans per year on a pay-per-scan basis, and to pay a minimum annual fee (including payments to our partners) of $58 million. The payment is expected to be guaranteed by a standby letter of credit in the amount of $58 million in favor of us.
>
> The Nanox Systems provided under this agreement will remain our property, and Intertrading Australia will only have a limited license to use the Nanox Systems. In addition, we must approve in writing

> any sublicense granted under this agreement. We undertake to provide billing, radiology and maintenance services and to provide training for a local medical professional workforce to operate the Nanox.ARC.
>
> The agreement will be in effect for three years from the date of the agreement and is renewable for an additional term of three years with both parties' mutual consent. The agreement may be terminated by notice of the non-breaching party in case of a material breach of a party's material obligations, or by either party in case of the bankruptcy or insolvency of the other party.

75. On February 27, 2020, the SEC's Division of Corporation Finance, Office of Life Sciences, filed a letter addressed to Defendant Poliakine. This letter shows that the SEC considered the Nano-X's statement regarding MSaaS Agreements to be material. In the letter, the SEC said that it had reviewed the February 18, 2020 Draft Registration Statement and added, "[w]e note you have entered into a Medical Screening as a Service Agreement with Intertrading Australia Ltd. Please file this agreement as an exhibit to your filing or tell us why you do not believe it is required to be filed. Please refer to Item 601(b)(10) of Regulation S-K."

76. On March 6, 2020, Nano-X responded to the SEC, writing that Gateway is important to Nano-X's business, but the MSaaS Agreement was made in the ordinary course of business and Nano-X is not substantially dependent on it. Nano-X also wrote that the MSaaS agreement with Gateway did not qualify under the definition of "material contract" provided under Item 601(b)(10) of Regulation S-K. Therefore, Nano-X believed that it was not required to be filed as an exhibit to the Registration Statement. Nano-X further advised the SEC that it would update its disclosure on page 88 of the Registration Statement to clarify that the MSaaS Agreement was entered into with Gateway.

77. In its Registration Statement, Nano-X list eight distribution contracts that purportedly amount to approximately $163.8 million in annual commitments to execute the MSaaS agreements.

78. Although Defendants boast having customers on four continents, Defendants do not have any MSaaS agreements with any U.S. based entities. They plan to deploy 3,000 Nanox Systems through a "strategic partnership" with USARAD, a teleradiology company. This nebulous arrangement does not explain how Nano-X will distribute its machines to providers in the U.S. Defendants do not list a single hospital system, clinic, or even an urgent care facility where they will place a Nano-X System with USARAD's help.

79. Despite the lack of detail about their plans in the U.S., the entirety of the Defendants' efforts to obtain regulatory approval have been through Accelerated Device, an FDA accredited third-party, and not from regulators in countries where they allegedly have MSaaS agreements.

80. When describing their distributers, Defendants stated that they had selected appropriate partners, who are already in the medical imaging field, know their local market, and are capable financially and otherwise to carry out the MSaaS business model. At a minimum, this would require the distributers to have experience with medical imaging devices and connections with healthcare providers. Financially, a distributer would also need to demonstrate to a bank that it is creditworthy for a large commercial loan. Unless both conditions are met, it does not make sense for an entity to sign one of the Defendants' MSaaS agreements.

81. Gateway is not experienced in medical imaging devices or with healthcare providers. Gateway does not hold itself out as a medical device distributor. Gateway's website only notes that it is a wholesaler and distributer in Australasia for the following sectors: FMCG

("fast moving consumer goods"); drinks; beauty and cosmetics; health food, supplement, and sports nutrition; luxury hair care; and consumer electronics, audio products, and commercial electronics. Therefore, it was ill-suited and would be unable to carry out an MSaaS agreement.

82. In addition, the Muddy Waters Report found that the LATAM Business Development Group Ltd. is not experienced in the medical device field and its MSaaS agreement reportedly had exceedingly favorable terms. Muddy Waters found that LATAM is the distributor of choice for Peritech Pharma's hemorrhoid and anal itching gels but could not highlight a similar agreement in the medical imaging or device sectors. Also, the enforceability of the standby letter of credit from LATAM Business Development Group Ltd. was conditioned upon the parties finalizing within 90 days of the *date of the agreement*, in mutually agreed form, the terms and conditions of the statement of work, the system requirement specifications and the service level agreement. According to the Registration Statement, the agreement was dated July 6, 2020, which means the parties would have had to have finalized the agreement by October 4, 2020. Because Nano-X had not received regulatory approval for the Nanox.ARC, let alone submitted an application for approval in any jurisdiction, there was nothing to finalize.

83. The Muddy Waters Report also found that Nano-X's partner Promedica Bioelectronics S.R.L. could not guarantee $29 million in annual payments. Muddy Waters reviewed Italian regulatory filings, which showed that Promedica had €4.6 million in revenues in 2018 (the most recent year for which figures are available) and garnered only €31k in profit. Furthermore, with just €250,160 in cash on its balance sheet, Muddy Waters concluded that Promedica could not guarantee $29 million in annual payments to Nano-X.

84. Similarly, the Muddy Waters Report casts doubt on Nano-X claims that APR 1998 S.L. of Spain could guarantee $11.4 million in annual revenues to Nano-X and a letter of credit

for the same amount. Muddy Waters reviewed Spanish regulatory filings, and found that the company, which performs maintenance on diagnostic imaging machines, generated just €5.4 million revenues and €1.1 million in operating profit in 2018 (the most recent year for which results were available). S.L also had a mere €322,530 in cash and short-term investments at year-end 2018. The Muddy Waters Report concluded that it would be highly unlikely that any bank would give a $11.4 million letter of credit to such an enterprise.

85. JSC Roel Group is also an unsuitable distribution partner. Muddy Waters Research reviewed Russian sources and revealed that rather than being a medical device company, JSC Roel Group is a holding company that primarily owns industrial businesses, like a Russian electric motor manufacturer and a textile plant. The Muddy Waters Report concluded that Roel has no discernable strong ties to hospitals, apart from a single fertility clinic. The Muddy Waters Report also revealed that the company's founder, Vladamir Dorokhin, had a history of bankruptcies and was accused of committing fraud while he was the Deputy General Finance Director of Moscow's Sheremetyevo Airport.

86. The Muddy Waters Report also examined the Golden Vine International Company and concluded that it also lacked industry expertise and was incapable of providing the stated service levels. The Muddy Waters Report cites Nano-X s June 2020 press release, which announced their agreement with Golden Vine. The press release claimed that the business was led by Pepi Liao, "a second generation of the Liao Wan Lung (廖萬隆), family,who is the founder and chairman of CB CERATIZIT – one of the largest global suppliers of Tungsten Carbide to leading medical imaging vendors such as Siemens, Fuji Seiko, Samsungand others." However, Muddy Waters found that Pepi Liao's only professional experience was in the hotel industry and had little

apparent connection to the family business. Accordingly, Golden Vine International Company could not provide $29 million in annual sales.

87. On information and belief, Nano-X has yet to derive any income from the eight distribution contracts listed in its Registration Statement, over two years after they were purportedly signed.

F. Defendants Had a Duty To Disclose that Nano-X Could Not Receive Regulatory Approval in the Near-term and that the Distributors Lacked Experience in the Medical-Imaging Sector.

88. Pursuant to Item 303 of Regulation S-K, 17 C.F.R. § 229.303(ii), Nano-X and the Individual Defendants had an affirmative, independent duty to disclose "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." By failing to disclose that: (1) that regulatory approval for the Nanox System could not be imminent; (2) that the distributers for their products lacked experience in the medical-imaging sector and were therefore ill-suited to carry out the MSaaS business plan, there was no plausible pathway to carry out Nano-X's business model and the prospective marketability and profitability of the Nanox System, if any, was far more uncertain than investors were led to believe, Nano-X and the Individual Defendants failed to satisfy this duty. These omissions give rise to Lead Plaintiffs' claims because they render statements by Nano-X, including the ones enumerated *infra* ¶¶ 96-125 materially false and/or misleading.

89. Pursuant to Item 105 of Regulation S-K, 17 C.F.R. § 229.105, Nano-X and the Individual Defendants had an affirmative, independent duty to disclose in the Prospectus the company's most significant risk factors that make the offering speculative or risky.

90. By failing to disclose that: (1) that regulatory approval for the Nano-X System could not be imminent given known deficiencies; (2) that the distributers for their products lacked experience in the medical-imaging sector and were therefore inappropriate partners; and (3) that their MSaaS agreements were not definite, and that these agreements would not generate revenue in the near-term either from charging for medical scans or by way of exacting fees from their distributers' letters of credit, there was no plausible pathway to carry out the Nano-X's business model and the prospective marketability and profitability of the Nanox System, if any, was far more uncertain than investors were led to believe, Nano-X and the Individual Defendants failed to satisfy this duty.

91. Since, according to the Registration Statements, Nano-X's "core digital X-ray source technology is the basis of [their] business. The Nanox.Arc currently under development is being designed to integrate our X-ray source technology into a medical imaging device for commercial use. As a result, "the success of [their] business plan is highly dependent on [their]ability to develop, manufacture and commercialize our X-ray source technology and related products and services, such as the Nanox.Arc and the Nanox.Cloud, and [their] failure to do so could cause [their] business to fail," the omissions described in this paragraph posed a grave threat to Nano-X's business and were among the most significant factors making an investment in Nano-X. The Registration Statement further told investors that, "[w]e estimate that effectively stimulating market interest in our Nanox System will require deploying at least 5,000 to 10,000 Nanox.ARC units. In addition, we estimate that a minimum installed base of at least 1,000 Nanox.ARC units will be needed to support our business during the initial deployment, assuming we enter into at least one licensing agreement on commercially reasonable terms. We may never achieve any of these thresholds for units deployed in the near-to-mid-term at any level or at all,

which may cause our business to fail[,]" the omissions described in this paragraph posed a grave threat to Nano-X's business and were among the most significant factors making an investment in Nano-X. These omissions give rise to Lead Plaintiffs' claims because they render statements by Defendants, including the ones enumerated *infra* ¶¶ 96-125 materially misleading.

V. MATERIAL MISSTATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

92. Defendants issued a series of pervasive and material misstatements and omissions about Nano-X's distributors, their regulatory applications, and their technology in their public filings and statements. These material misstatements and omissions created the false impression that Nano-X's distributors were experienced in the medical imaging field, the Nano-X System was close to regulatory approval and commercialization, that the MSaaS agreements were definite, and that these agreements would generate revenue in the near-term either through completing scans or by way of the distributers' letters of credit. None of these impressions is accurate.

A. The Registration Statement

93. The Registration Statement, signed by the Individual Defendants, discussed Nano-X's commercial agreements, stating in part:

> **MSaaS Agreements**
>
> ***We have entered into eight MSaaS Agreements to deploy 4,520 Nanox Systems in eleven regions as described in the table below.*** Under the terms of eachagreement, we grant the other party a limited, non-transferable, exclusive, sub- licensable right to access and operate the Nanox System in the region indicated forsuch party. ***We undertake to provide the specified number of Nanox Systems to each entity as indicated in the table below based on agreed shipment schedules, subject to local regulatory approval and material compliance with acceptance test protocol (the "conditions precedent").*** The other party undertakes to deploy the systems to provide a minimum number of scans per year (based on 7 scans per dayand 23 days per month) on a pay-per-scan basis at a minimum of $14 per scan, andto pay a minimum annual fee (including payments to our partners) in the amount indicated in the table below. The payments are expected to be guaranteed by a standby letter of credit in the amount equal to the minimum annual fee in favor of us after receipt of the conditions precedent.

The Nanox Systems provided under each agreement will remain our property, and the other party will only have a limited license to use the Nanox Systems. In addition, we must approve in writing any sublicense granted under this agreement. We undertake to provide billing, radiology and maintenance services and to providetraining for a local medical professional workforce to operate the Nanox.ARC.

Each agreement will be in effect for multiple years, ranging from three to six years from the date of the applicable agreement, and is renewable for an additional multi-year term with both parties' mutual consent as indicated in the table below. Each agreement may be terminated by notice of the non-breaching party in case of a material breach of a party's material obligations, or by either party in case of the bankruptcy or insolvency of the other party.

Entity	Date of MSaaS Agreement	Region	Number of Nanox Systems to be Provided	Minimum Annual Fee and Amount of Letter of Credit (approximate)	Initial Term	Renewal Term
The Gateway Group, Ltd.	February 11, 2020	Australia, New Zealand and Norway	1,000	$58 million	3 years	3 years
Golden Vine International Company, Ltd.	May 28, 2020	Taiwan and Singapore	500	Up to $29 million	5 years	5 years*
Promedica Bioelectronics s.r.l.	May 29, 2020	Italy	500	$29 million	4 years	3 years
JSC Roel Group	May 29, 2020	Russian Federation	500	$12.6 million	5 years	5 years
Clarity Medical Solution, a division of "Grodnobioproduct" LLC	June 4, 2020	Belarus	100	$3.7 million	3 years	4 years
Gold Rush	June 16, 2020	South Africa	500	$15.5 million	3 years	3 years
LATAM Business Development Group Ltd.	July 6, 2020	Brazil	1,000	$4.8 million (9 million Letter of Credit) in Year 1 $14.5 million in Year 2 $24.2 million in Year 3***	6 years	3 years
APR 1998 S.L.	July 25, 2020	Spain	420	$11.4 million	5 years	5 years**
TOTAL			4,520	$163.8 million		

* The MSaaS Agreement with Golden Vine International Company, Ltd. may also be terminated by either party upon notice stipulating that the notifying party has come to the conclusion, based on market evidence, that there is no business merit for the Nanox.ARC in Taiwan or Singapore.

** The MSaaS Agreement with APR 1998 S.L. may also be terminated by the service provider at the end of a six-month trial period by sending within five days a formal notice to the Company if trial results are not satisfactory.

*** The enforceability of the standby letter of credit from LATAM Business Development Group Ltd. in our favor is also conditioned upon the parties finalizing within 90 days of the date of

> the agreement, in mutually agreed form, the terms and conditions of the statement of work, the system requirement specifications and the service level agreement.

94. The statements referenced in paragraph 93 were false and/or misleading because even if Nano-X had regulatory approval for the Nanox.ARC, the distributors referenced in paragraph 98 would not be able to execute Nano-X's MSaaS business plan. Defendants failed to disclose that its distributers, specifically Gateway, Golden Vine International Company, Ltd. ("Golden Vine") and the LATAM Business Development Group Ltd. ("LATAM") lacked experience in the medical imaging industry and medical device fields. These three companies represented half of the Defendants' projected annual fees. Defendants also hid the fact that the LATAM Business Development Group Ltd., Nano-X's distributor in Brazil, only employed people in Israel.

95. Defendants further hid the fact Gateway does not hold itself out as a medical device distributor. Gateway's website only notes that it is a wholesaler and distributer in Australasia for the following sectors: FMCG ("fast moving consumer goods"); drinks; beauty and cosmetics; health food, supplement, and sports nutrition; luxury hair care; and consumer electronics, audio products, and commercial electronics.

B. <u>September 14, 2020 – Jefferies Virtual Asia Forum</u>

96. On September 14, 2020, Defendants participated in the Jefferies Virtual Asia Forum. Upon information and belief, Defendants attached the presentation shown at the Jefferies Virtual Asia Forum as an exhibit to a Form 6-K filed September 22, 2020.

97. At this virtual forum Defendant Poliakine discussed the MSaaS agreements and the regulatory process, stating:

> In terms of regulatory approval, and I will talk about it later, this is a medical device. You need to go through a regulatory clearance, FDA in the U.S., CE in Europe and many others in each country

> where we have contract with. I am very pleased to tell you that we have 11 countries that we signed contracts with. And because of that, we need to get clearances to go to business in each one of those countries. Specifically in the U.S., we submitted the initial submission of single source to the FDA. **And we expect that overall, in multiple touches during the first half of next year, we'll be ready to go to prime time.**
>
> Of course, we are going to push and try to propel this market. But I want to tell you that today, we have about 5,000 actually units, 4,520 units. **That was a little bit a few weeks ago that are already committed by customers in 11 countries, and I'll touch upon it in a minute. And that actually provides for a meaningful, I would say, obligated revenue of service for a long term, 3 years minimum, subject to local regulatory approvals and accepted tests in the said territory.**
>
> (emphasis added)

98. The statements above in paragraph 97 were false and/or misleading because Defendant Poliakine misrepresented Nano-X's agreements with its distributers and Nano-X's commercial viability. The statement, "we expect that overall, in multiple touches during the first half of next year, we'll be ready to go to prime time," was materially false and misleading because on September 14, 2020, Defendants had *only* submitted a 510(k) application for approval for their non-commercial product. Nano-X struggled to gain clearance for this straightforward device.

99. The expectation for rapid approval from the FDA were false given the Defendants' known deficiencies with their applications. Because Defendants were preparing a 510(k) submission and were required to demonstrate that the Nanox.ARC was substantially equivalent to already marketed devices, Defendants knew or, but for their deliberate recklessness, should have known, that statements concerning approval for the 510(k) application for the Nanox.ARC and being ready to go prime time" were false and misleading.

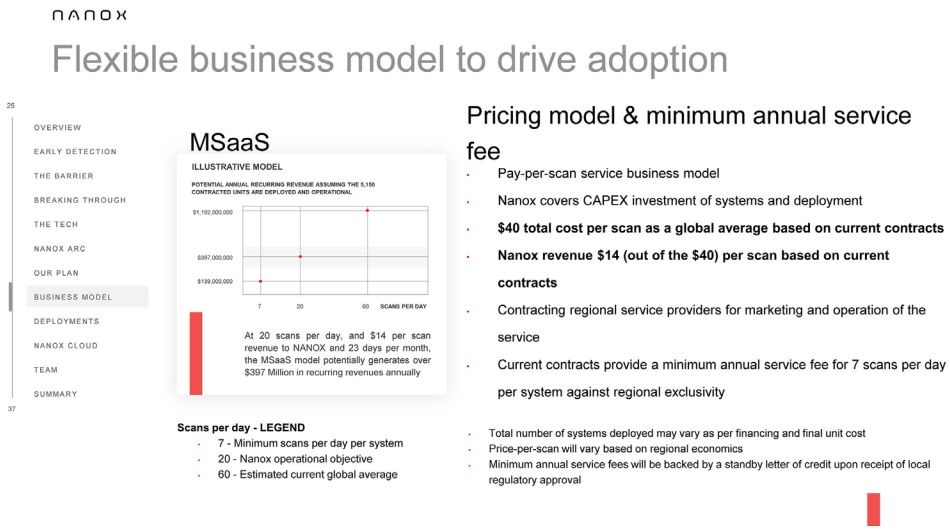
100. Defendant Poliakine also omitted the fact that this application was only for a device that could only perform X-rays of the hand, wrist, and fingers from a fixed position, objectively

inferior to the predicate devices cited by Nano-X's application. Despite not even applying for approval for their commercial product in the United States, submitting an approval application that came close to the promised functionality of the Nanox.ARC, or applying for approval in any country covered by one of the MSaaS agreements, Defendant Poliakine created the false impression that regulatory approval was imminent.

101. The statements above in paragraph 97 were also false and/or misleading because Nano-X distributors would not be able to execute Nano-X's MSaaS business plan. By characterizing the distributers as "committed by customers" who would provide "meaningful" and "obligated revenue of service for a long term," Defendant Poliakine created the false impression that the MSaaS agreements were definite, would generate revenue in the near-term either by charging for scans or by way of the distributers' letters of credit, and were made with entities who had experience in the medical imagine or device sectors. These statements were misleading because they created the impression that the distributors listed in the Registration Statement were appropriate partners with experience in the field when they lacked industry experience and would be unable to execute Nano-X's business plan.

102. Although, Defendant Poliakine added that these agreements were subject to local regulatory approvals and acceptance tests, in the context of his misstatements about the state of the Nano-X's regulatory approval process and the distributors, this cautionary language was rendered ineffectual.

103. Upon information and belief, the presentation included the following slide:



104. The statements above in paragraph 103 were false and/pr misleading because they misrepresented the role of the distributers in the MSaaS business model. Specifically, the statement, "[c]ontracting regional service providers for marketing and operation of the service," creates the false impression that the Defendants are entering agreements with service providers as opposed to distributors or intermediaries.

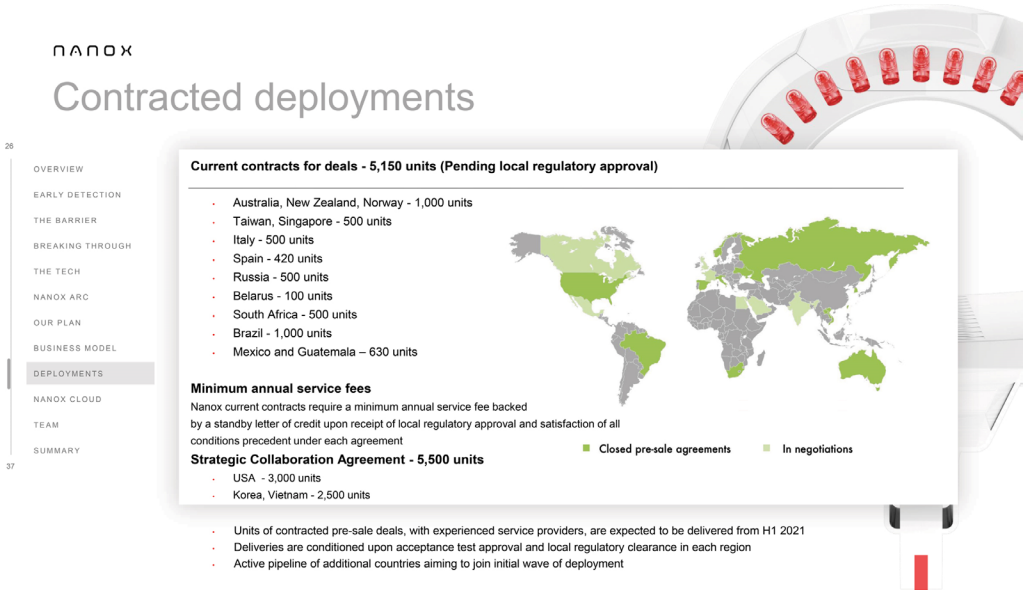
105. The statements contained in this slide create the false impression that the distributers listed in the Registration Statement and discussed during the September 14, 2020 presentation were medical providers that would perform diagnostic services. These statements created the impression that the distributors listed in the Registration Statement were appropriate partners with experience in the field when they lacked experience in the industry and were ill-suited to execute the Nano-X's business plan. Under the MSaaS agreements, the distributers are entirely responsible for deploying the Nanox System, an unproven and unlicensed machine, into a highly regulated medical-imaging sector, and ensuring that unidentified medical providers will deliver a minimum number of daily scans in short order.

106. Although the slide mentions that letters of credit backing these agreements were subject to local regulatory approval, in the context Defendant Poliakine's statements previous statements regarding Nano-X's regulatory approval process, this cautionary language was rendered ineffectual.

107. Defendant Poliakine continued with the presentation before the Jefferies Virtual Asia Forum, stating:

> The next slide is actually connecting the model into, I would call it, reality. So as you can see, we already, as I said, signed and committed -- we have commitments for over 5,000 units by customers. Those commitments, as I said, are pending by local regulatory approval and the acceptance test. You can see the countries. You can see the distribution of systems. And I can just tell you that in each country we chose after a lot of negotiation, what we believe to be the **appropriate partner, partners that are already in the field, they know their own local market, and they are capable financially and otherwise to carry out our business model**. And not only that, we also ask them to provide a standby letter of credit to support their activities in terms of minimum quantities.

108. Upon information and belief, a copy of the above referenced slide addressing Nano-X's MSaaS agreement is below:



109. The statements above in paragraphs 107 and 108 were false and/or misleading because they misrepresent Nano-X's agreements with its distributers and Nano-X's commercial viability. Describing the distributors as "appropriate partner, partners that are already in the field, they know their own local market, and they are capable financially and otherwise to carry out our business model" were false given that they lacked experience in the industry making them unable to execute the MSaaS business plan.

110. Defendant Poliakine did not disclose that its distributers lacked experience in the medical imaging and device sectors. Defendant Poliakine also hid the fact the LATAM Business Development Group Ltd., Nano-X's distributor in Brazil, only employed people in Israel and that Golden Vine lacked experience in the medical imaging and device sectors. Defendants further hid the fact Gateway does not hold itself out as a medical device distributor. Gateway's website only notes that it is a wholesaler and distributer in Australasia for the following sectors: FMCG ("fast moving consumer goods"); drinks; beauty and cosmetics; health food, supplement, and sports nutrition; luxury hair care; and consumer electronics, audio products, and commercial electronics. Therefore, these distributors were ill-suited and would be unable to carry out an MSaaS agreement.

111. Upon information and belief, the below slide highlighting Gateway, was included in the presentation at the September 14, 2020 forum:

112. The statements above in paragraph 111 were false and/or misleading because Gateway was not an appropriate partner with experience in the field, and was unable to execute the MSaaS business model. Defendants misrepresent Nano-X's agreement with its largest distributer and misled investors about Gateway. First, the $27 million minimum annual service fees to Nano-X listed on this slide is a marked reduction from the minimum annual fee of $58 million listed in the Registration Statement. This vast discrepancy is unexplained and indicates the MsaaS contract with Gateway was not a definitive agreement.

113. Second, the statements contained in paragraph 111 were false and/or misleading because they create the impression that Gateway is one of Australia's largest distributors of medical devices. Defendants only cite one company, BrainsWay, to support this contention. BrainsWay neither has a medical imaging product, nor does BrainsWay provide medical imaging services in Australia, Norway, New Zealand, or anywhere else. Defendants further omitted that Gateway does not hold itself out as a medical device distributor. Gateway's website only notes that it is a wholesaler and distributer in Australasia for the following sectors: FMCG ("fast moving

consumer goods"); drinks; beauty and cosmetics; health food, supplement, and sports nutrition; luxury hair care; and consumer electronics, audio products, and commercial electronics.

C. <u>September 15, 2020 – Cantor Fitzgerald 2020 Global Health Conference</u>

114. On the morning of September 15, 2020, Defendants participated in the Cantor Fitzgerald 2020 Global Health Conference. Upon information and belief, Defendants filed the presentation shown at the Cantor Fitzgerald 2020 Global Health Conference on September 22, 2020 as an exhibit to a Form 6-K.[1]

115. Defendant Poliakine discussed the MSaaS agreements at this virtual forum, stating:

> So for instance, in Australia, we put 1,000 of those; in America, in some places, 500, another 500, and so on and so forth. And I can tell you that this has been very, very easy sale because the value proposition here is huge. **And we are very lucky because we're sitting on more than 5,000 units obligated by contract. And not only that, there is a letter of credit that is going to obligate our service providers for the minimum scans per day.** I'll touch upon it.

116. The statements above in paragraph 115 were false and/pr misleading because the distributors identified in the Registration Statement were not appropriate partners with experience in the field and, even if the Nanox.ARC were approved, these distributors would be unable to execute the MSaaS business model.

117. At this virtual forum Defendant Poliakine also discussed the regulatory process, stating:

> And the next slide is actually talking about the regulatory paths. As I said, we are going to -- we already signed contract in more than, I think, 11 countries. And of course, it's a medical device. We need to get clearance. We believe that during the first half of next year, not only will we get the FDA clearance via 510(k), but also we'll get

[1] [1] According to the Form 6-K, filed on September 22, 2020, the above referenced presentation was made at the Oppenheimer Fall Healthcare Life Science & MedTech Summit. The report is titled, "Dawn of early detection healthcare: Investor Presentation September 2020." Upon information and belief, Defendants used the same materials at all their September 2020 presentations.

> other countries where we sign contract and we'll start our business. **That's our belief. Of course, FDA and regulatory is always timing type of risk. But we feel, based on also our previous experience, that this is a very reasonable assumption.**

118. The statements above in paragraph 117 were false and/or misleading because expectations that the FDA would approve the Nanox.ARC in the near-term were false given known deficiencies with Defendants' submissions. Defendant Poliakine statement that based on previous experience it was a "reasonable assumption" Nano-X would get FDA clearance "in the first half of next year" was misleading because the Defendants had no such experience with the FDA. The only experience regulatory experience Defendants had was receiving a major deficiency letter in March 2020 not from the FDA, but from an accredited third-party for their 510(k) application for their single-source Nanox.ARC. Defendants did not submit anything to the FDA before December 2020 for their non-commercial product. The submission for the multi-source Nanox.ARC had not even been filed anywhere.

119. The statement "[b]ut also we'll get [regulatory approval in] other countries where we sign contract and we'll start our business," was also false and/or misleading because the Defendants had no experience with medical device regulators in other countries. Defendants had not submitted any applications in other countries and therefore there was no reasonable basis to state that, "We believe that during the first half of next year [we will get clearance in countries outside of the United States]."

120. The application Defendants submitted to the FDA was for a very basic device that could not even perform a chest X-ray, let alone anything approaching the diagnostic testing capabilities promised by the multiple-source Nanox.ARC. The statements above in paragraph 117 omitted these facts about the application, misleading investors about the Defendants' technology and creating the false impression that regulatory approval was imminent. These statements were

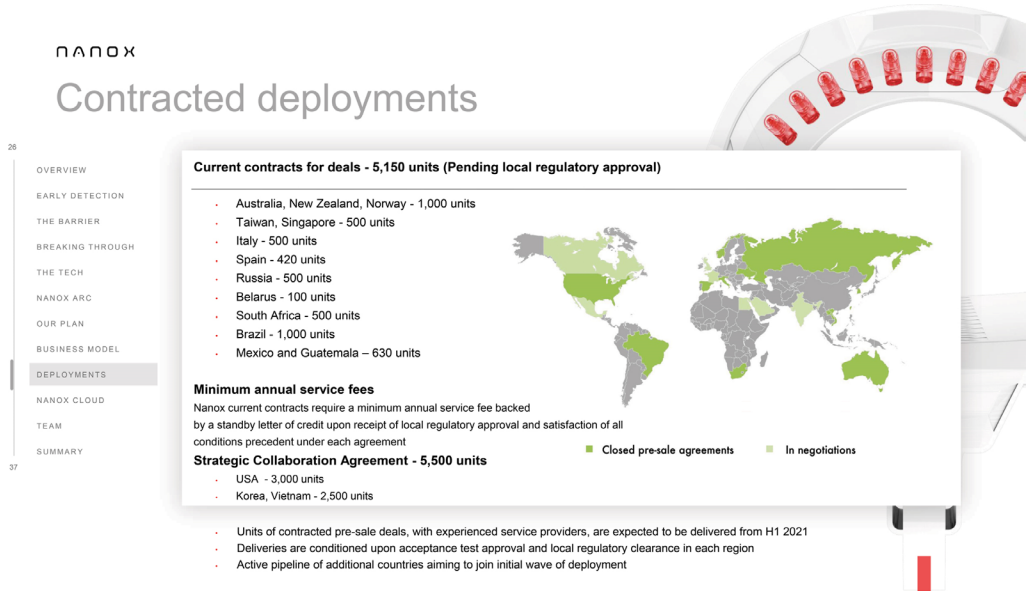
false and misleading because there was no possibility that the Defendants could "start" their business in the first half of 2021.

121. Because Defendants were preparing a 510(k) submission and were required to demonstrate that the Nanox.ARC was substantially equivalent to already marketed devices, Defendants knew or, but for their deliberate recklessness, should have known, that there was no basis to state that getting FDA approval was a "reasonable assumption."

122. Defendant Poliakine also discussed Nano-X's distributors, stating:

> The next slide is actually connecting the model with reality. So even though we didn't make many products, we have so many customers. What you see on the top side of this slide. These are all customers that committed in countries, and you see the different countries and different units. **And I can only tell you that each one of the service providers, in our opinion, has the capacity, the financial capabilities and, I would say, they're eager to go on with this business model because this is what they believe can get huge traction in their own market. And so we're talking about all of those customers with a signed contract ready for us to pass the regulatory approval in their own country and start shooting scans.**

123. Upon information and belief, a copy of the above referenced slide addressing Nano-X's contracts is below:



124. The statements above in paragraphs 122 and 123 were false and/or misleading because the distributors identified in the Registration Statement and referred to the slide in Paragraph 128 were not appropriate partners with experience in the field and, even if the Nanox.ARC were approved, these distributors would be unable to execute the MSaaS business model. Defendant Poliakine calling the distributers "service providers" was false and/or misleading because they do not provide any medical services. Under the terms of an MSaaS agreement, Nano-X grants a distributor a limited, non-transferable, exclusive, sublicensable right to access and operate the Nanox System in a specific geographic region. The distributer then undertakes to deploy the system to provide a minimum number of scans per year" and enters a sublicense with a hospital, clinic, or other provider of medical imaging service. Nano-X must approve any sublicense granted under these agreements. The distributers, particularly Gateway, lacked experience in the medical imaging and device sectors and are not "service providers."

125. The statements above in paragraphs 122 that "each one of the service providers, in our opinion, has the capacity, the financial capabilities…to go on with this business model" was false and misleading because the distributors were unable to guarantee the purported letters of credit. Nano-X's partner Promedica Bioelectronics S.R.L. could not guarantee $29 million in annual payments. Italian regulatory filings show that Promedica had €4.6 million in revenues in 2018 (the most recent year for which figures are available) and garnered only €31k in profit. Furthermore, with just €250,160 in cash on its balance sheet, Promedica could not guarantee $29 million in annual payments to Nano-X. Similarly, APR 1998 S.L. of Spain could not guarantee $11.4 million in annual revenues to Nano-X and a letter of credit for the same amount. Spanish regulatory filings show that the company, which performs maintenance on diagnostic imaging machines, generated just €5.4 million revenues and €1.1 million in operating profit in 2018 (the

most recent year for which results were available). S.L also had a mere €322,530 in cash and short-term investments at year-end 2018. The Muddy Waters Report concluded that it would be highly unlikely that any bank would give a $11.4 million letter of credit to such an enterprise.

VI. THE TRUTH IS REVEALED

126. On September 15, 2020, analyst firm Citron Research, which has exposed several fraudulent companies published an exposé, titled "Nano-X Imaging (NNOX) A Complete Farce on the Market – Theranos 2.0" (the "Citron Report") that revealed, among other things, "NNOX's commercial agreements may sound nice on the surface, but these appear to be no more than fake customers."

127. The Citron Report also revealed the truth about the Nano-X's FDA application. The report showed that Nano-X hasn't produced enough evidence to show its product will work and that its research and development expenditure was too small for a breakthrough on the level management was boasting. It emphasized Nano-X's lack of regulatory approval and questioned its technology claims, stating that: "[t]here is not one scientific paper of submission that would back up any of [Nano-X's] claims.

> NNOX has never published any data showing their machine's images compared to images from a standard CT scanner. There is not one scientific paper or submission that would back up any of these claims. As a matter of fact, we have not even seen proof of the product and have only seen a mockup drawing of what this machine is supposed to look like.

128. Defendants filed a 510(k) premarket submission, claiming that their device was substantially equivalent to a legally marketed device, as opposed to an application for a novel product. This submission compares a proposed device with one or more similar legally marked devices to support an applicant's claims that its device is substantially equivalent to some predicate device. Defendants filed their submission in January 2020 and received a major deficiency letter

in March 2020 because they failed to provide required data. While the FDA approves 85% of all 510(k) submissions it receives, Nano-X could not obtain this straightforward FDA clearance. In fact, it turned that the device was barely equivalent to similar X-ray machines already on the market.

129. The Citron Report also revealed that Defendants misled investors about their customers: "Despite not having any unique technology, FDA approval, or even a working model, Nano-X's appears to have put out distribution agreements." The report further stated that, "these agreements are worthless unless Nano-X's can deliver on its ridiculous claims." The report found that Gateway, Nano-X's largest distributor, did not even operate in the medical device sector. Nano-X's had purportedly had an MSaaS contract with Gateway to deploy 1,000 Nano-X Systems throughout Australia, Norway, and New Zealand and Gateway would pay Nano-X a minimum annual fee of $58 million for three years (or $27 million per the September 2022 persentation). This would represent 35% of Nano-X's total annual payments. Pursuant to the terms of their agreement, Gateway would procure a letter of credit in the amount of the annual fee. However, Gateway markets itself as wholesaler and distributors for the following sectors: fast-moving consumer goods (FMCG); drinks; beauty and cosmetics; health food, supplement, and sports nutrition; luxury hair care; and consumer electronics, audio products, and commercial electronics. This led Citron Research to conclude that Gateway was a "fake customer."

130. The Citron Report also examined Golden Vine and LATAM, who were listed in the Registration Statement as committing to deploy 1500 Nanox Systems with annual fees up to $29 million and $24.2 million respectively, and similarly determined that they were also "fake customers." Based upon its web presence, Citron concluded that Golden Vine lacked experience in the medical imaging and device sectors and therefore would be unable to carry out the terms of

an MSaaS agreement. Citron also reviewed LATAM's records, which revealed that Nano-X's Brazilian distributor only employed three people who were based in Israel. This led Citron Research to conclude that Gold Vine and LATAM were similarly "fake customers."

131. On this news, Nano-X's share price fell $12.41 per share, or more than 25%, over the next two trading days to close at $36.80 per share on September 16, 2020, damaging investors.

VII. POST-CLASS PERIOD DISCLOSURES

A. The Muddy Waters Report

132. On September 22, 2020, analyst firm Muddy Waters Research, published a lengthy exposé, titled "Nanox: Star Trek, Theranos, and Nikola" (the "Muddy Waters Report"). The Muddy Waters Report buttressed the conclusions of the Citron Report, including interviews with radiologists, Nano-X's partners, a Nano-X Advisory Board member, and a former Nano-X employee. The Muddy Waters Report identified serious deficiencies with the customers Nano-X listed in its prospectus, noting that the agreements provided significant contingencies in favor of the distributors, the listed entities lacked industry expertise, and they were financially incapable of obtaining the required standby letters of credit and providing stated service levels. Nano-X also misrepresented its partnerships with an Israeli Hospital, teleradiology company, and medical image analysis company. The radiologists interviewed for the Muddy Waters Report voiced a profound lack of belief in Nano-X claims and technological validity and Nano-X's ability to meet its 2021 distribution deadlines.

1. Partnership Details Cast Significant Doubt on Nano-X's Operations.

133. The Muddy Waters report casts doubt on Nano-X's MSaaS agreements, noting that the agreements provided significant contingencies in favor of the distributors, the listed entities lacked industry expertise, and were incapable of providing stated service levels.

134. Muddy Waters highlighted the circumstances under which partners could abandon their agreement. In addition to regulatory approval and testing conditions, Nano-X's agreements

with its second and fourth-largest distributers, Golden Vine International Company Ltd. and APR 1998 S.L., have significant conditions in themthat allow the partners to terminate the agreement, calling into question $30 million out of the $163.8 million in annual revenue agreements. The MSaaS Agreement with Golden Vine International Company, Ltd. may also be terminated by either party upon notice stipulating that the notifying party has concluded, based on market evidence, that there is no business merit for the Nanox.ARC in Taiwan or Singapore. The MSaaS Agreement with APR 1998 S.L. may also be terminated by the service provider at the end of a six-month trial period by sending within five days a formal notice to Nano-X if trial results are not satisfactory.

135. In addition, the Muddy Waters Report found that the LATAM Business Development Group Ltd. is not experienced in the medical device field and its MSaaS agreement reportedly had exceedingly favorable terms. Muddy Waters found that LATAM is the distributor of choice for Peritech Pharma's hemorrhoid and anal itching gels but could not highlight a similar agreement in the medical imaging or device sectors. Also, the enforceability of the standby letter of credit from LATAM Business Development Group Ltd. was conditioned upon the parties finalizing within 90 days of the *date of the agreement*, in mutually agreed form, the terms and conditions of the statement of work, the system requirement specifications and the service level agreement. According to the Registration Statement, the agreement was dated July 6, 2020, which means the parties would have had to have finalized the agreement by October 4, 2020. Because Nano-X had not received regulatory approval for the Nanox.ARC, let alone submitted an application for approval in any jurisdiction, there was nothing to finalize.

136. The Muddy Waters Report also found that Nano-X's partner Promedica Bioelectronics S.R.L. could not guarantee $29 million in annual payments. Muddy Waters

reviewed Italian regulatory filings, which showed that Promedica had €4.6 million in revenues in 2018 (the most recent year for which figures are available) and garnered only €31k in profit. Furthermore, with just €250,160 in cash on its balance sheet, Muddy Waters concluded that Promedica could not guarantee $29 million in annual payments to Nano-X.

137. Similarly, the Muddy Waters Report casts doubt on Nano-X claims that APR 1998 S.L. of Spain could guarantee $11.4 million in annual revenues to Nano-X and a letter of credit for the same amount. Muddy Waters reviewed Spanish regulatory filings, and found that the company, which performs maintenance on diagnostic imaging machines, generated just €5.4 million revenues and €1.1 million in operating profit in 2018 (the most recent year for which results were available). S.L also had a mere €322,530 in cash and short-term investments at year-end 2018. The Muddy Waters Report concluded that it would be highly unlikely that any bank would give a $11.4 million letter of credit to such an enterprise.

138. JSC Roel Group is also an unsuitable distribution partner. Muddy Waters Research reviewed Russian sources and revealed that rather than being a medical device company, JSC Roel Group is a holding company that primarily owns industrial businesses, like a Russian electric motor manufacturer and a textile plant. The Muddy Waters Report concluded that Roel has no discernable strong ties to hospitals, apart from a single fertility clinic. The Muddy Waters Report also revealed that the company's founder, Vladamir Dorokhin, had a history of bankruptcies and was accused of committing fraud while he was the Deputy General Finance Director of Moscow's Sheremetyevo Airport.

139. The Muddy Waters Report also examined the Golden Vine International Company and concluded that it also lacked industry expertise and was incapable of providing the stated service levels. The Muddy Waters Report cites Nano-X s June 2020 press release, which

announced their agreement with Golden Vine. The press release claimed that the business was led by Pepi Liao, "a second generation of the Liao Wan Lung (廖萬隆), family,who is the founder and chairman of CB CERATIZIT – one of the largest global suppliers of Tungsten Carbide to leading medical imaging vendors such as Siemens, Fuji Seiko, Samsungand others." However, Muddy Waters found that Pepi Liao's only professional experience was in the hotel industry and had little apparent connection to the family business. Accordingly, Golden Vine International Company could not provide $29 million in annual sales.

2. Nano-X Misrepresented its Partnerships.

140. Muddy Waters Research conducted several interviews with Nano-X's partners and found that Nano-X misled the public about its collaborations with Hadassah Hospital, Cure Metrix, and USARAD.

a. Hadassah

141. The Muddy Waters Report raised the following issues with the purported Hadassah partnership:

> Another halo NNOX is using to try to legitimize itself is that of "Nobel Peace Prize-nominated" Hadassah hospital. We are convinced that this partnership has been greatly misrepresented. As background, the chairman of NNOX's audit committee is the chairman of the board of Hadassah. He also received options exercisable at $2.21 per share. We have tried multiple routes to understand what exactly is happening with the ARC at Hadassah, yet we have been unable to getanybody to even confirm that the device is operating at the hospital. Some investors are apparently under the impression that data from studies at Hadassah forms the backbone of NNOX's 510(k) submission. However, that misunderstands the timeline of events and the submission process.
>
> Hadassah's Executive Chairman, Erez Meltzer, is also Chairman of NNOX's Audit Committee. Echoing other bargain-basement deals select individuals have gotten, he received 40,234 NNOX warrants with a strike price of $2.21.[31] These are now worth approximately

$1.1 million. But we think something is amiss in NNOX's partnership with Hadassah.

In its prospectus, NNOX stated, "we introduced a working prototype of the Nanox.ARC in February 2020". In a conference presentation last week, Poliakine included a photo (below right) which he claimed is the working prototype that is taking "beautiful images" right now at Hadassah.

Moreover, a sell-side analyst attempting to rebut the Citron report claimed that theNanox prototype "has been in place at Hadassah hospital in Jerusalem" and "[d]ata used for theFDA was gathered at this site." However, these admissions fail to match NNOX's own claimed development timeline

First, NNOX's Third Party Review submission was made in January 2020, according the prospectus. Second, February 2020 was the claimed development date for Nanox's working prototype. Third, formal collaboration with Hadassah did not begin until April 2020. Takentogether, these facts make it impossible for NNOX to have tested its working prototype anywhere, much less Hadassah Hospital, before 510(k) submission.

To add to what we view as a suspicious lack of clarity on this partnership, discussions with multiple radiologists at Hadassah Hospital failed to confirm that a NNOX machine exists there. Our investigators made contact with two Hadassah doctors being paid by Nanox. These doctorscould not or would not acknowledge that there was a NNOX machine being used on patients, citing agreements with the company. Given that NNOX has publicized this

> partnership, we do not see how affirming that the machine is being used at Hadassah would violate an NDA."
>
> A former Hadassah radiologist said that he hadn't heard of NNOX, but he asked his ex- colleagues currently at Hadassah about the company. He told our investigator that neither of the Hadassah radiologists had heard of Nanox. He also added that one of the Hadassah doctors who had refused to speak with us was "invested in the company." The radiologist went on to call Nanox's website "nothing convincing," stating that "there's not much evidence that it's a working machine."
>
> An X-ray technician at Hadassah stated, "If you talk about the CT scan machine, so in Hadassahit's Philips company. I don't know or think that this product is in use at hospitals in [I]srael.. I can ask at Hadassah the doctors or tecnitions [sic] about it. Because it's not my department. Like I told you I'm in Intervention Radiology at angiography. We do procedure's [sic] like embolization of bleeding, drainage, chemoemboliation [sic] of tumors, fixing vessels, stenting, etc."
>
> [One of the radiologists that Muddy Waters interviewed stated]: "I saw the [Hadassah] doctor speaking, but again, he doesn't talk about the product. He doesn't say what its done in his institution. He says, 'It could', or 'this could', or the 'potential is great. I'm happy to collaborate,' but doesn't say what the product is. Doesn't say where the product is. Doesn't say concrete things that he's doing with it. I listened tohim. It's vapor. The first thing it would be, if I was that guy—I've been that guy, the testimonial guy—I will tell you the concrete things I'm doing with it. He didn't say that once."

b. Curemetrix

142. Nano-X's partnership with Curemetrix is, "little more than a handful of phone calls and clerical emails because nothing has materialized from Nano-X's end." Muddy Waters Research spoke with three employees at Curemetrix, all of whom verified that their "agreement" consisted primarily of a hope of co-operating in the future. All three of the employees Muddy Waters contacted confirmed they have not received images from Nano-X, not even for compatibility testing purposes. One stated:

> "Every month we write them. 'We're ready.' You know, 'Would you like to send your image and we can run our CAD [computer-aided diagnosis] through your system?' Andthey've just kind of ghosted us… They're like, 'Oh, we don't have images ready yet. It's still in production.' I mean, this is from March until now, six months."

143. The same Curemetrix employee further stated, "I feel like it's a misnomer to say that we are even collaborating with them at this point. It's more like they're just using our name on their advertisement, which makes me very upset."

c. USARAD

144. One radiologist interviewed for the Muddy Waters Report revealed that Nano-X had mislead investors about its partnership with USARAD. USARAD is a teleradiology company that offers board certified radiologists who can provide radiology reports and personalized teleradiology services in the United States. However, Defendants have claimed that the USARAD would be able to deploy 3,000 Nanox Systems. The radiologist interviewed by Muddy Waters debunked this claim, stating:

> "Yes, you don't do that [sell machines as teleradiology company]. Teleradiology, what you're doing, basically, is just trying to read the images. You're not involved in anything else… It's like me selling machines."

3. <u>Radiologists Voiced a Profound Lack of Belief in Nano-X's Claims and Technological Validity.</u>

145. Muddy Waters interviewed five radiologists and a Nano-X advisory board member about the Nanox.ARC. Their reactions ranged from skepticism to outright derision. They expressed disbelief about the claims and skepticism about the Nanox.ARC's functionality. Two of the radiologists believed that the money raised in the IPO was for R&D purposes, likening the status of Nano-X's progress to that of a company doing an angel investment round. Muddy Waters

viewed this as highly problematic, given that the company continually proclaims that it has a supposedly near-finished product:

> The radiologists uniformly wondered why there are few images that NNOX has made public outside of the rudimentary X-rays that we discuss [later in the report]. They highlighted that this runsin stark contrast to industry practice. Even an otherwise optimistic member of NNOX's Advisory Board admitted to not having yet seen images: "No, I have not seen a live demonstration… I have not seen a working device or any pictures or images from or computerized tomography pictures of this, or images with this device yet. I don't think that's something that is doneyet. As far as I know, no one has gotten scanned by this device yet."
>
> "They haven't shown they can do anything except for the extremity X-ray. On the other hand, the rest of it is bluster. Will they be able to build it? Will they be able to build it atscale? Will it actually work as a CT scanner? Nobody knows."
>
> "A buddy of mine was also looking at this company. He has CT patents himself. He ran the CT business for [large imaging company], ran the MR business for [large imaging company], very close colleague of [NNOX Advisory Board member]. He reads these things and he just laughs out loud. He says it's like there's not an ounce of credibility in anything they're claiming."
>
> "This thing just seems so outrageous and there's not a single article, there's no images anywhere. Where's the images? If you're doing it, there's images. Because the other thing would be is, you would have to say that your images have to bethe same or better, but you're claiming it's all better. As a radiologist and someone who does this for the last 40 years, I'm ashamed to say, it's too good to be true. That's how Ilooked at it."
>
> "I've seen with companies like Siemens, a real company, and small companies, including ourselves and our other companies at RSNA [Radiology Society of North America], the first thing people always show is images. That's the first thing I ask for. You can tell me, 'Our machine does this, that, and the other,' and then I say, 'Show methe images.' Then I say, 'How do these images compare to the other images?' The next question you ask, 'How accurate is it?'"
>
> "What you're showing me was just basic X-rays, that's probably the easiestthing that we do in radiology or plane films. So I wouldn't bank them generating any x- ray pictures as the ability to do much

higher-level imaging in a satisfactory or potentiallyFDA approved way."

"They're basically claiming they could do everything for everything. I wouldn't believe that if Siemens told me that, with all of their money as well as their research."

"This whole thing here, like I said, the first thing is, when you tell me you've got a company that's going to make X-ray, CT, angiography, mammography and you don't have any images, and you're also going to do AI, billing, and reading, and everything'slike an iPhone to take a picture, to listen to music? That's what an iPhone is, but medicine's not iPhones."

"That is a statement by someone who does not know what he's talking about, because one of the key things about mammography is you got to get your boobs squished. We compress the breast because that is needed in order to spread the breast tissue to acquire the picture. That is an inherent part of the exam. You cannot just lay somebody down in a CT scanner machine and obtain a mammogram. That's ridiculous. I cannot fathom that that machine could be used for that purpose at all. Maybe that you could modify, but you're not going to replace the mammogram machine with that one little prototype. I just don't see that and doing X-rays with that kind of a machine with a gantry that appears to be somewhat thin, it doesn't even have the proper field of view to do an X-ray, say, of your entire abdomen. A lot of that, it just doesn't make sense to me."

"They're two totally different types of technology. X-ray image isn't so hard to produce, but the CT scan image is a lot more work because it's not just the image acquisition, but after it's acquired, there are algorithms called kernels, that you use to post-process the image, and also to create different renderings of the data. That's a process. The third thing is, to create mammogram images, is taking it to another level. [laughs] Mammography is, in some ways, the most difficult because the resolution has to be so high, and there are a lot of nuances to the equipment. With the grids, and the exposure time, and a lot of different factors that go into it. I think that they're attempting to apply the new, this novel X-ray tube, to apply it for multiple different X-ray modalities, but… It would be three completely different types of machines to do an X-ray, to do a CT scan, or to do a mammogram."

4. The Nanox System can only perform Rudimentary X-rays.

146. The Muddy Waters Report also raised the question, why has Nano-X shown only rudimentary X-rays. The images Nano-X revealed, were criticized by the radiologists in the Muddy Waters report as entirely underwhelming, on par with antiquated X-ray technology already available in cheap machines:

> "The easiest thing in the world to do is take an X-ray. People make very cheap X-ray machines. That's the first thing is, all you're seeing is you're taking an X-rayof a foot. That's the easiest thing in the world. Remember, Roentgen took an X-ray of a hand in 1895. That was the first image he ever made, his wife's hand with a ring on. To make an X-ray of a foot, and it looked nothing special, but to say you can take an X-ray of a foot is not exactly stellar technology."
>
> "They're making this thing seem like it's a CT scanner that will do what a CT does. It might be able to do what a planar X-ray does. In which case it's an interesting but very expensive version of a machine that can do an X-ray. On the other hand, if it does what a CT does it could change the world which is why these people are spending orinvesting this money but there's no evidence it's ever going to be able to do that."
>
> "You don't take pre-orders unless you have a product. Where did these images come from, these three images? Did they come from Hadassah Hospital? If Hadassah is doing stuff why haven't we seen them? If I was their advisor working with them and you didn'tsee images, you'd know the machine wasn't working. "I think this could easily be sitting in a room unbuilt, sitting in the room potentially built, but not approved to be used in humans, sitting in a room approved to be used in humans, but not working or it could be in there doing X-rays all day long, just plain old, simple X-rays all day long. They're doing feasibilities they're testing and collecting data for approval. It could be any of those things. I'd like to know which one it is. It is not a CT scan, it is an X-ray."
>
> "Everything they've shown, it's an X-ray, they talk CT… Their claims about cost and availability are ludicrous, lots of inaccuracies and confusion, and inflated claims, but itseems like they can make an X-ray."
>
> "Their kVp and their mAs, I mean, the radiation is lower, but… I want to see the actual machine with the control panels and how you take the pictures. I mean, nowadays, anybody can make something

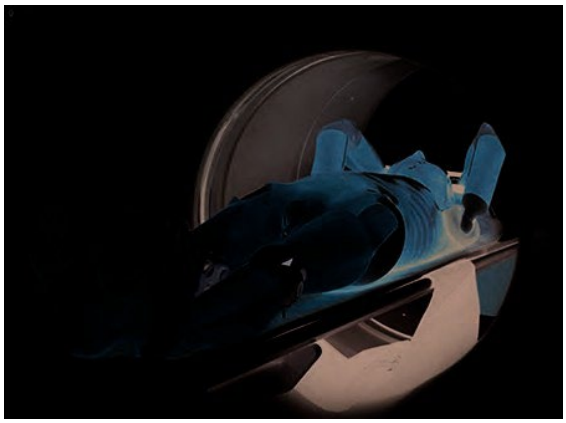
> up like those… They can totally just type it in and there's no way to prove it unless they show you a picture of their X-ray machine panel and that is the actual setting."

5. <u>Nano-X Seems to Have Used Somebody Else's Images to Fake its "Live Demo."</u>

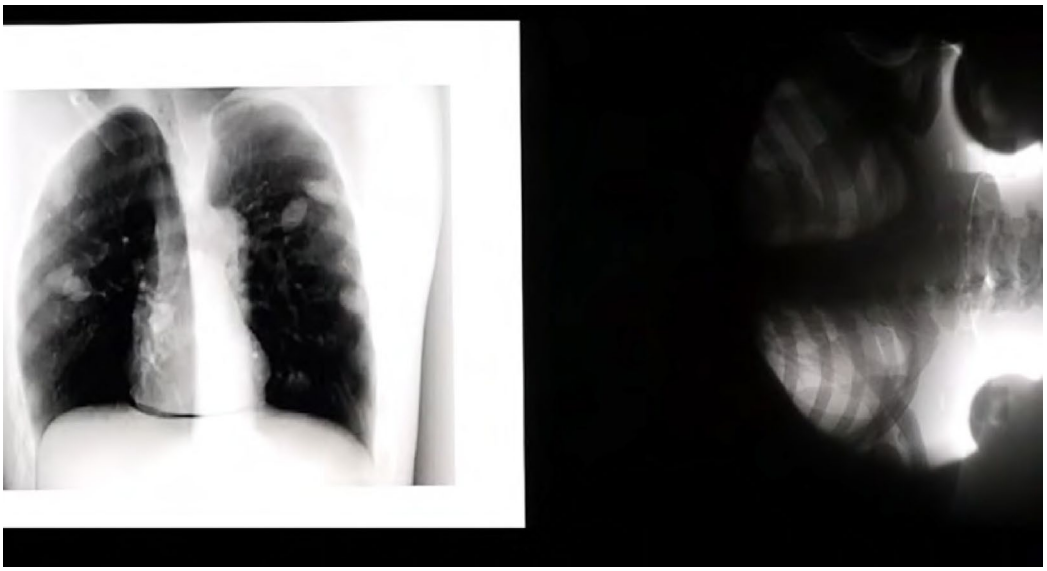
147. Nano-X published a video in February 2020, showing a test dummy, known as a phantom, in an unidentified room being passed over by a prototype of the Nanox.ARC. The video then cuts to full-screen shots of a black-and- white, rotating chest image on the left side of the screen and a stationary image of a chest on the right. Four radiologists that Muddy Waters spoke with opined that the imaging footage is fake:

> In the beginning of the video, the phantom is laying with its arms across its chest as theNanox.ARC moves down the torso:

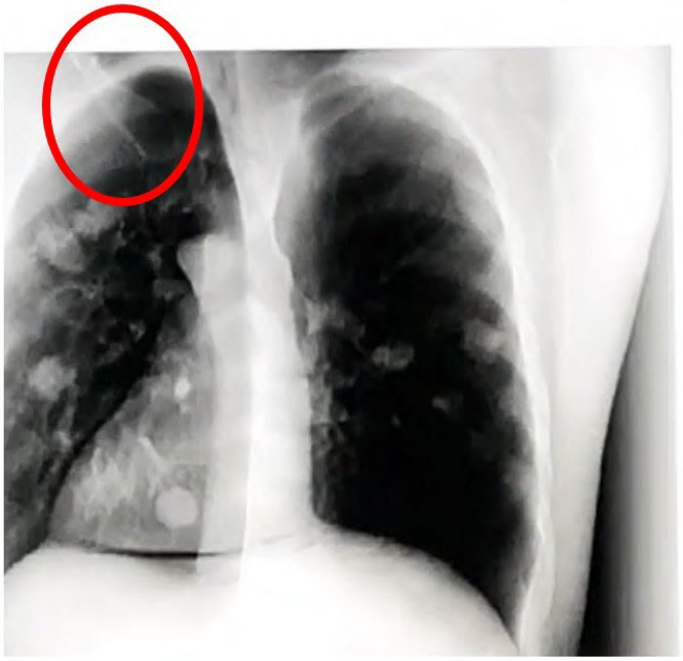
Three radiologists noted that this position is never how chest CT scans are done, as the arms get in the way of the chest image, suggesting that knowledge of radiology or radiography is lacking at NNOX. (Below is a photograph of the same make and model phantom positioned properly fora scan.)



One radiologist stated that there appeared to be something wrong with the way the ARC acquired the image in the top right once the machine advanced past the mid-torso: "It's just one big blur." Regardless, the video then switches to two shots that take up the entire screen:



The image on the left rotates, while the one on the right remains largely the same. However, allfour radiologists recognized glaring issues with the image on the left: The arms are pointed upward. You can easily tell this by looking at the collarbones in the image:



Thus, this image is clearly not the phantom being scanned. To add to the amateurishness of the apparent deception, there are masses displayed in the lungs on the left image that are missing from the right image. This provides additional support that these two images come from different sources, according to the four radiologists. Two radiologists hypothesized that instead of being 3D tomosynthesis, as claimed, the image on the left is instead a reconstructed CT image "from some other scan or technology". Note that every radiologist with whom we spoke stated that the ARC is not capable of CT scans, despite the company's claims; and therefore, any CT image would necessarily be from an outside source.

One radiologist found a similar type of phantom to the one being used, a Kyoto Kagaku PBU-60:the radiologist noted that because the phantom was closed-body and shipped free of nodules, there was no way for someone to insert such objects in the chest, meaning the image on the left was not of the same phantom, if even a phantom at all. Another radiologist also stated that the angle of rotation being used in the left image was likely selected to impress a non-medical observer with clear contours of the chest, but it was useless from a radiologist's perspective.

Meanwhile, as far as the right-hand image is concerned, all four radiologists characterized it asexceedingly poor. One remarked that this image was "terrible… no radiologist would want to read images look like that". Two radiologists opined that the chest image seemed not to advance with the movement of the Nanox.ARC. One

> remarked that for this reason, "those images certainly weren't acquired then and there."
>
> After viewing the footage, one radiologist said bluntly, "That is very fraudulent for them to dothat video… I suspect neither of these pictures are from that machine."

148. After the Muddy Water's Report, the February 2020 video discussed by the radiologists was removed and replaced with a shorter video on the Defendants' Vimeo page. Upon information and belief, the first video was published by A-Labs Advisory & Finance Ltd. ("A-Labs"). A-Labs provided Defendants with consulting services in connection with various transactions, such as private placement and the public offering.

149. On October 1, 2020, Muddy Waters published a YouTube video comparing Nano-X's two demonstration videos. In a chest imaging demonstration video, discussed above, Nano-X claimed to show an example of the Nanox.ARC's 3D tomography capability with a rotating view of a phantom's chest. However, the rotating image clearly had its arms up, as opposed to crossing its chest as displayed in the video, and the radiologists Muddy Waters interviewed doubted that the images came from the Nanox.ARC. The new video only contained the right-hand X-ray, which two radiologists called unreadable. The original video also showed panning shots of Hadassah hospital and walkthrough footage of its hallways, stating that it was recorded in December 2019. This was removed, presumably in response to the Muddy Waters Report, as it questioned whether Nano-X's testing was conducted at Hadassah.

6. Nano-X Mislead Investors About its Ability to Make 2021 Estimates.

150. The radiologists who were interviewed for the Muddy Waters Report dismissed Nano-X's touted 2021 distribution estimates. They cited the lack of documentation and evaluation of the product's capabilities, namely given there are no studies using the actual Nanox.ARC in a

research hospital setting, coupled with the lack of any peer-reviewed, published material discussing the efficacy of the machine when used on humans:

> "I think the likelihood [of a 1,000-unit 2021 rollout] would be low. If it's August now, and they haven't developed a working model…"
>
> "It's a lengthy process. If somebody would like to launch the thing by next year in the US market, I don't think that's possible."
>
> "It was interesting, because when you read through their website, they're talking about wanting to distribute… and I'm like, where are you putting these? Like you haven't even shown a machine that does anything. So how are you going to have a thousand machines anywhere, you know, in the second quarter of 2021, or whatever it was?"

B. Nano-X's RSNA Demonstration

151. On December 4, 2020, the Nano-X participated in the Radiology Society of North America's ("RSNA") annual meeting. RSNA is a non-profit organization and an international society of radiologists, medical physicists and other medical imaging professionals representing 31 radiologic subspecialties from 145 countries around the world.

152. Livestreaming from Israel, Defendant Poliakine touted the firm's ceramic digital x-ray tube that allegedly costs about $100 per unit compared to the up $150,000 for glass tubes that are commonly in use.

153. During the presentation, he successfully imaged his own wrist in real-time using the single-source Nanox.ARC (what was later disclosed to be the Nanox Cart). A lengthy portion of the nearly 30-minute presentation was also dedicated to comparing images of a phantom taken at Schneider Children's Hospital in Israel to those produced with the same model allegedly using the Nanox.ARC prototype.

154. The market was not particularly impressed by this display, as Nano-X saw only a modest gain in its stock price. It closed at $57.04/share from an opening price 56.37/share.

C. Nano-X's 20-F

155. On April 6, 2021, Defendants filed their Form 20-F with the SEC. Defendants disclosed that after Accelerated Devices submitted the 510(K) application, on January 30, 2021, the FDA requested additional information. The FDA required Defendants to address certain deficiencies and provide additional support regarding the intended use of the single-source Nanox.ARC and the comparability to the predicate device. Defendants submitted their response to these requests on March 1, 2021 and received clearance from the FDA to market the single-source Nanox.ARC on April 1, 2021. However, the single-source Nanox.ARC is actually called the "Nanox Cart X-ray System" (or the "Nanox Cart"). For the first time in their Form 20-F, Defendants referred to the device by the named submitted to the FDA.

156. The 20-F also stated the following:

> We have identified material weaknesses in our internal control over financial reporting that could, if not remediated, result in material misstatements in our financial statements. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

D. FDA Approves the Single Source Nanox.ARC aka the "Nanox Cart"

157. On or about May 5, 2021, the FDA released its clearance letter for the Nanox Cart along with Nano-X's March 1, 2021 submission file. The letter and the file revealed that the device is not, in fact, an arch shaped machine with a single X-ray tube, but rather a stationary mobile X-ray unit that cannot operate without being plugged into an electrical outlet and can only be used in a fixed position. The indicated use is for the Nanox Cart is for X-ray examinations of hands, wrists, and fingers only. It is explicitly not intended for "general radiographic X-ray examinations…or for mammographic, angiographic, interventional, or fluoroscopic applications."

158. The predicate devices—what Nano-X told the FDA its machine is substantial like—are Mobile X-ray systems manufactured by GE and by Carestream Health Inc. Both of those devices are indicated for use in all general-purpose X-ray diagnostic procedures. Therefore, the Nanox Cart is barely equivalent to X-ray machines already on the market.

E. NaNOx Chronicles reveals that Nano-X's 510(k) Submission is Highly Problematic.

159. On May 10, 2021, Richard Roe published a review of Nano-X's 510(k) submission for the Nanox.Cart on his blog titled "NaNOx Chronicles." The author publishes under a pseudonym and discloses that he has a financial interest or investment positions in one or more securities (and/or options, swaps, and other derivatives associated with one or more of these securities) that are related to the contents of his blog. The postings echo the sentiments expressed in the Citron Report and the Muddy Waters Report.

160. Roe's summary and analysis of the 510(k) submission is as follows:

> **The name of the predicate device is wrong**
>
> The name of the predicate device, cleared under K021016, is AMX-4 Plus Mobile X-ray System, not AMX-4 Mobile X-ray System as claimed by the Summary. What else is incorrect, if Nanox cannot even get the name of the predicate device right? The "Plus" system is the upgraded model. The predicate of the Plus model is AMX-3 Mobile X-ray System, K802047, another GE system. The chair of Nanox Advisory Board is a former GE executive.
>
> **A micro-controller Arduino Mega 256 does not exist**
>
> Table 1 claims that Nanox.Cart uses a micro-controller Arduino Mega 256 that "controls the Nanox Cart X-ray System's functionality and GUI display." No such micro-controller exists. There is an Arduino Mega 2560 micro-controller **board** designed for hobbyists that uses the old and cheap ATmega2560 micro-controller released more than 15 years ago. Quite novel.

The target angle of 0 degrees in Table 1 is non-sensical (a typo) and contradicts the 16 degrees value in Table 2

The target, or anode, angle is a very important characteristic of an X-ray tube, as it determines focal size and beam width, strength and composition. At zero degrees, the tube will be completely unusable. It is one mistake that Nanox should not have made, if its "X-ray source technology [were] the basis of [its] business" (page 9, annual report).

The maximum tube voltage for the predicate device in Table 1 is incorrect

Table 1 claims that the maximum tube voltage for the predicate device is 100 kV, which clearly contradicts the 125 kV value from the "kV range" section in the same table. The actual value is 130 kV (from the tech specs of the HRT09 tube).

The power output of the reference device is annoying

Table 2 states that the power output of the reference device is 4.8 kW @ **104** msec, which is incorrect (a typo) and it should be "@100 msec," which is the standard (for example, IEC 60613:2010).

The X-ray source used by Nanox.Cart is still a mystery

There is no mention in the summary of any of the non-sensical descriptions that Nanox typically uses for its proposed X-ray source - digital, MEMs, silicon, semi-conductor, novel, etc. Table 2 claims that the "Nanox Tube" is similar to "Xinray CNT Tube," but that is **incorrect** based on the data in Table 2, as the CNT tube is 60x as powerful (4.8kW vs 0.08kW), capable of substantially higher tube voltage (110kVp vs 40kVp) and current. Table 1 mentions that Nanox.Cart uses a "Nano-x's **Cold Cathode** tube" in the system description, but the tube type/model in both Table 1 and 2 is given as "Nanox Tube" (no cold-cathode here) and there is no tube model (Nanox' web site shows at least 4 completely different and incompatible "Nanox tubes" that look remarkably similar to regular industrial/dental hot-cathode tubes).

The mention of an X-ray source in the intended use is non-sensical

The description of the device's intended use begins with the non-sensical statement

The product is intended as an X-ray source for diagnosis.

The product is a mobile X-ray system - FDA product code IZL - not a X-ray source (which almost exclusively means an X-ray tube in the context of modern diagnostic equipment - other sources could be radioactive isotopes, synchrotrons, etc). The product is supposed to include many more components other than an X-ray tube, as confirmed by the "system components" section in Table 1, for example, It appears this statement was intentionally inserted by Nanox to confuse investors and possibly subvert the 510(k) clearance process.

The single-source Nanox device is cleared only for hands, wrists, and fingers, on adult patients only

Both Table 1 and Table 2 claim that the intended use of the device is **similar** to that of the predicate and reference devices. But that is incorrect and contradicts the actual description of the intended use, as the device is cleared for a very limited subset of examinations, while both the predicate and reference devices can do **all general purpose X-ray diagnostic** procedures. In fact, the limitation for use explicitly states:

*This device **is not intended for general radiographic X-ray examinations** other than the indicated use...*
So much for Nanox curing cancer.

The Nanox device is cleared to work with only one detector model, which appears unsuitable and has to be purchased separately

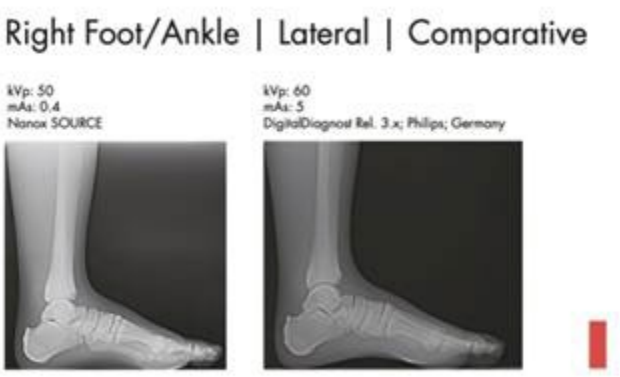
There is a bit of problem with the tech specs of the detector that Nanox has chosen to work with its device. The summary states:
*The Nanox Cart is **specified and designed** to operate **only** with a Flat Panel Digital X-ray Detector Model EVS3643, manufactured by DRTECH Inc.*

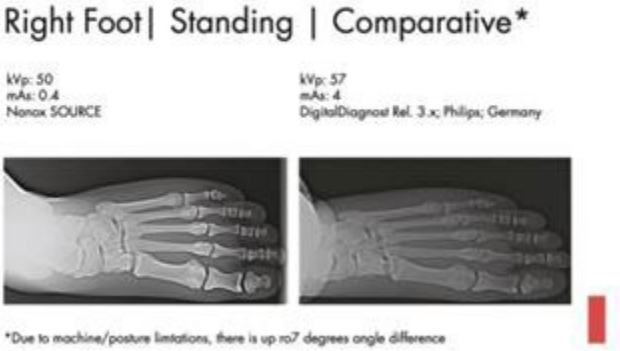
The summary of the detector clearance specifies that the X-ray system using it must have tube voltage equal or higher to 40 kVp, so Nanox.Cart **barely complies** (its tube voltage is fixed at 40 kVp per Table 1 and 2). What is more troubling is that the generator "mA Range" used in the detector clearance is specified as "10mA ~ 1000mA," which Nanox Cart **fails to meet,** as it cannot deliver more than 2mA (implied by 2mAs and 1 second).
More importantly, this detector cannot be used for diagnostic purposes on a live subject by the proposed multi-source Nanox.ARC

device, as it is too slow and takes about 5 seconds to capture and transfer an image. A 45-image tomosynthesis of a wrist, for example, would take at least 4 minutes, if the RSNA 2020 demo were anywhere close to reality.
Finally, the lowest quote for this detector, obtained in the gray market - new, but from unauthorized distributors and without warranty - is about $20,000. So much for being "**cheap**."

Many of the images supposedly made with the single-source device in the annual report and in investor presentations are likely fake.

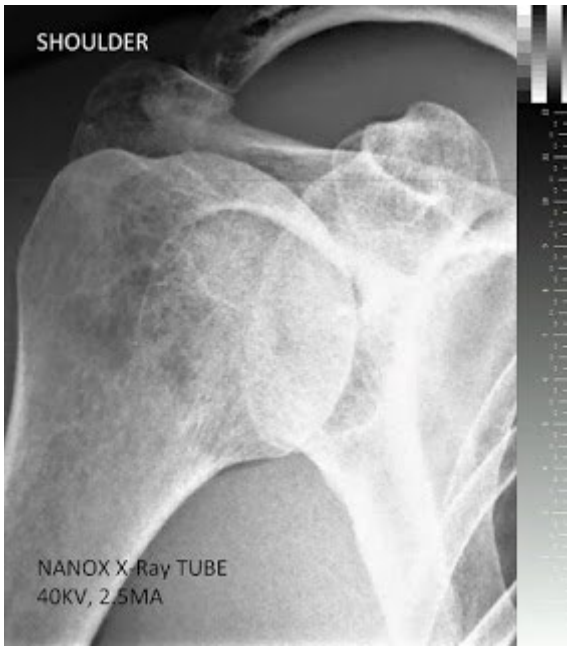
According to the annual report, [Nanox has] *generated the images below with the Nanox.ARC using a* ***single X-ray tube*** *on an imaging phantom* (page 61).





However, none of these images were generated by the device that received clearance, as the device tube voltage is limited to 40 kVp (so the 50 kVp tube voltage in the images is impossible). Moreover, the device is not cleared for ankle/foot examinations.

Here is another image, from Nanox investor presentations, that is impossible to create by the device that got cleared.



First, the device is not cleared for shoulder examinations. Second, the 2.5mA reading exceeds the maximum device tube current of 2mA.

The mobility of the device is questionable

The device is cleared under the IZL product code, but it is not truly mobile/transportable. The device description states:

The system facilitates X-ray examinations in situations where it is not possible or feasible to transport the patient to a ward with fixed equipment

But the device has no battery, unlike its predicate - it is as mobile as the length of the cord (less mobile than a regular vacuum cleaner).

The device is "similar" to the predicate device, except that it is not

The section "Substantial Equivalence Discussion" is somewhat confusing. The section argues that the device is equivalent except that it is not.

*The technical characteristics of the System **are not different** from the predicate device **except for** the fixed Source-to-image Distance,*

Field of view, aperture, focal spot size, and the fixed tube voltage and reduced maximum exposure current-time product.

Virtually all technical characteristics of the two devices are significantly different, and, it can be argued, raise many questions of effectiveness. Table 1, for example, confusingly states that the fixed tube voltage or the current time product (or charge) are similar to the significantly wider ranges that are needed in practice and can be obtained from the predicate device. For example, typical "technique charts" for digital detectors stipulate tube voltages of least 46 kVp for the intended use (adult fingers/wrist/hands), above the 40 kVp limit of the device.

The device requires cooling fluid

This must be surprising to Nanox investors who are led to believe by the CEO that a cold-cathode tube, even if real, runs somehow cooler than a regular hot-cathode tube of the same power.

The intended use contradicts the disclosures in the SEC filings

Nanox implies in its SEC filings that the device will not be commercialized, and so the statement that the indented use is to perform diagnostic radiographic examinations is misleading.

Specifically, Nanox states in its SEC filings:

the multiple-source Nanox.ARC [rather than this cleared Nanox.Cart device] ... *will be our commercial imaging system* (page 2, Prospectus).

Nanox has further revealed that, while not intending commercial distribution of the cleared device, it is using the 510(k) submission as part of its regulatory strategy, a step in a *multi-step approach to the regulatory clearance process* (page 1, Prospectus), *where* the apparent ultimate goal is to induce the FDA to clear the "the multiple-source Nanox.ARC" device by first creating a predicate out of the Nanox.Cart.

Therefore, any statements by Nanox about "indications for use" or intended use or intent to market the cleared device, other than an admission that the device is not intended to be marketed and the submission is simply a step in Nanox regulatory strategy, are problematic.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

A. Defendants Had No Basis to Make the Repeated Statements Did Regarding the 510(k) Application for the Nanox.ARC.

161. As alleged herein, Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of Nano-X were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

162. By virtue of their positions at Nano-X, the Individual Defendants had actual knowledge or reckless disregard for the discrepancies between Nano-X's internal knowledge about the regulatory applications for the Nanox.ARC and statements in the Nano-X Registration Statement, other public statements in SEC filings, and investor presentations. Because Defendants were preparing a 510(k) submission and were required to demonstrate that the Nanox.ARC was substantially equivalent to already marketed devices, Defendants knew or, but for their deliberate recklessness, should have known, that statements concerning approval for the 510(k) application for the Nanox.ARC and being ready for "prime time" were false and misleading.

163. Accordingly, the Individual Defendants had actual knowledge of materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, the Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of such Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Individual

Defendants knew or recklessly disregarded that materials facts were being misrepresented or omitted as described above.

164. By virtue of their positions at the Nano-X, the Individual Defendants had actual knowledge or reckless disregard for the discrepancies between Nano-X's internal knowledge about its regulatory applications and statements in the Nano-X Registration Statement, other public statements in SEC filings, and investor presentations. There is no basis to make the repeated claims that it was a "reasonable assumption" that Nano-X could get regulatory clearance to use the Nanox.ARC from the FDA and regulators in the eleven jurisdictions where they purportedly had MSaaS with distributors in the near future. There was no basis to tell investors that the Nanox System would be "ready to go prime time" in the immediate future.

165. Accordingly, the Individual Defendants had actual knowledge of materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, the Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of such Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Individual Defendants knew or recklessly disregarded that materials facts were being misrepresented or omitted as described above.

166. Alternatively, if somehow these facts were not expressly known to the Defendants in connection with making filings with the SEC and investor presentations, the Defendants were so extremely reckless in not knowing these material facts about their customers that scienter may be ascribed to them.

167. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the Nano-X's statements.

168. As a result of the dissemination of the false and misleading statements, the market price of Nano-X securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Nano-X's regulatory applications and customers, concealed by the Individual Defendants, Lead Plaintiffs and the other members of the Class purchased or otherwise acquired Nano-X's securities at artificially inflated prices.

B. Defendants Had No Basis to Make the Repeated Statements They Did Regarding Their Commercial Agreements.

169. As alleged herein, Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of Nano-X were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

170. By virtue of their positions at Nano-X, the Individual Defendants had actual knowledge or reckless disregard for the discrepancies between Nano-X's internal knowledge about the regulatory applications for the Nanox.ARC and statements in the Nano-X Registration Statement, other public statements in SEC filings, and investor presentations. Because Defendants were preparing a 510(k) submission and were required to demonstrate that the Nanox.ARC was substantially equivalent to already marketed devices, Defendants knew or, but for their deliberate recklessness, should have known, that statements concerning approval for the 510(k) application for the Nanox.ARC and being ready for "prime time" were false and misleading.

171. Accordingly, the Individual Defendants had actual knowledge of materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, the Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of such Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Individual Defendants knew or recklessly disregarded that materials facts were being misrepresented or omitted as described above.

172. By virtue of their positions at the Nano-X, the Individual Defendants had actual knowledge or reckless disregard for the discrepancies between Nano-X's internal knowledge about the Nano-X's MSaaS agreements and statements in the Nano-X Registration Statement, other public statements in SEC filings, and investor presentations. There is no basis to make the repeated claims that the MSaaS agreements were definite, that the customers were appropriate partners in the medical device space, and that the Nano-X could generate revenue in the near-term either from charging for medical scans or by way of exacting fees from their customers' letters of credit.

173. Accordingly, the Individual Defendants had actual knowledge of materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, the Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of such Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Individual

Defendants knew or recklessly disregarded that materials facts were being misrepresented or omitted as described above.

174. Alternatively, if somehow these facts were not expressly known to the Defendants in connection with making filings with the SEC and investor presentations, the Defendants were so extremely reckless in not knowing these material facts about their customers that scienter may be ascribed to them.

175. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of Nano-X's statements.

176. As a result of the dissemination of the false and misleading statements, the market price of Nano-X securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Nano-X's regulatory applications and customers, concealed by the Individual Defendants, Lead Plaintiffs and the other members of the Class purchased or otherwise acquired Nano-X's securities at artificially inflated prices.

C. The Importance of the Nano-X System Supports an Inference of Scienter

177. The Nanox.System is Nano-X's sole product. The proceeds raised from their IPO were allocated to: (1) "manufactur[ing] the initial wave of Nanox.ARC units planned for global deployment…;" (2) "the shipping, installation and deployment costs of the Nanox System . . ." and (3) "continued research and development of the Nanox.ARC…"

178. Defendants readily admit, "[o]ur core digital X-ray source technology is the basis of our business," [a]s a result, the success of our business plan is highly dependent on our ability to develop, manufacture and commercialize our X-ray source technology and related products and

services, such as the Nanox.Arc and the Nanox.Cloud, and our failure to do so could cause our business to fail."

179. Therefore, it is undisputed that the Nanox.Arc forms a critical part of Nano-X's core operations and facts regarding such critical matters, such as regulatory approval of the Nanox.Arc and contracts to deploy them, are known and understood by senior Nano-X management such as the Individual Defendants.

180. Thus, it is implausible, that the Defendants did not know: (1) that regulatory approval for the Nano-X System could not be imminent given known deficiencies with the regulatory applications; (2) that the distributers for their products were inappropriate partners with no experience in the medical-imaging field and, even if the Nanox.ARC were approved, these distributors would be unable to execute the MSaaS business model. It is implausible that they did not know the statements concerning the approval for the Nanox.Arc and their customer agreements were false when made. By virtue of their positions, they were required to have full knowledge of Nano-X's business relating to matters critical to the Nano-X's long-term viability which would affect future sources of income.

D. Defendants' Failure to Disclose Information That They Had a Clear Duty to Disclose Supports an Inference of Scienter

181. As discussed *supra* ¶¶88-91, pursuant to Item 303 of Regulation S-K, 17 C.F.R. §229.303(ii) and Item 105 of Regulation S-K, 17 C.F.R. §229.105, Defendants had an affirmative duty to disclose that: (1) that regulatory approval for the Nanox System was could not be imminent given known deficiencies with the FDA submissions; and (2) that the distributers for their products were not appropriate partners with experience in the medical-imaging field and, even if the Nanox.ARC were approved, these distributors would be unable to execute the MSaaS business

model. As a result, the prospective marketability and profitability of the Nanox.Arc, if any, was far more uncertain that investors were led to believe.

182. Both conscious misbehavior and recklessness may be inferred when the duty to disclose is clear and no disclosure is made.

IX. LOSS CAUSATION AND ECONOMIC LOSS

183. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated Nano-X's share price and operated as a fraud or deceit on acquirers of Nano-X securities. As detailed above, when the truth about Nano-X was revealed, the value of Nano-X securities declined precipitously as the prior artificial inflation no longer propped up its stock price. The decline in Nano-X's share price was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the Nano-X's price decline negates any inference that the loss suffered by Plaintiffs and other members of the Class was caused by changed market conditions, macroeconomic or industry factors or company-specific facts unrelated to the Defendant's fraudulent conduct. The economic loss, i.e., damages, suffered by Plaintiffs and other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate Nano-X's stock price and the subsequent significant decline in the value of Nano-X's share, price when Defendant's prior misrepresentations and other fraudulent conduct was revealed.

184. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and other Class members. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of Nano-X's business, operations, and financial condition, as alleged herein. Throughout the Class Period, Defendants publicly issued materially false and misleading statements and omitted material facts necessary to make Defendant's statements not

false or misleading, causing Nano-X's securities to be artificially inflated. Plaintiffs and other Class members purchased Nano-X's securities at those artificially inflated prices, causing them to suffer the damages complained of herein.

X. PRESUMPTION OF RELIANCE; FRAUD-ON-THE-MARKET

185. At all relevant times, the market for Nano-X securities was an efficient market for the following reasons, among others:

(a) Nano-X met the requirements for listing, and were listed and actively traded on NASDAQ, a highly efficient market;

(b) During the Class Period, Nano-X securities were actively traded, demonstrating a strong presumption of an efficient market;

(c) As a regulated issuer, Nano-X filed with the SEC periodic public reports during the Class Period;

(d) Nano-X regularly communicated with public investors via established market communication mechanisms; and

(e) Unexpected material news about Nano-X was rapidly reflected in and incorporated into Nano-X's stock price during the Class Period.

186. As a result of the foregoing, the market for Nano-X's securities promptly digested current information regarding Nano-X from all publicly available sources and reflected such information in Nano-X's stock price. Under these circumstances, all purchasers of Nano-X's securities during the Class Period suffered similar injury through their purchase of Nano-X's securities at artificially inflated prices, and a presumption of reliance applies.

187. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United*

States, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security. Here, the facts withheld are material because an investor would have considered Nano-X's financials and adequacy of internal controls over financial reporting when deciding whether to purchase and/or sell stock in Nano-X.

XI. NO SAFE HARBOR; INAPPLICABILITY OF BESPEAKS CAUTION DOCTRINE

188. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint.

189. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

190. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Nano-X who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by the Defendant were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the Defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

XII. CLASS ACTION ALLEGATIONS

191. Plaintiffs brings this action on behalf of all individuals and entities who purchased or otherwise acquired Nano-X's securities on the public market during the Class Period, and were damaged, excluding Defendant, Poliakine, Mayaan, current and former officers and directors of Nano-X, and each of their immediate family members, legal representatives, heirs, successors or assigns as well as all of Nano-X's parents, affiliates, subsidiaries, successors, predecessors, and any entity in which Nano-X or any of its current or former officers (including Poliakine and Mayaan), directors, or employees has or had, during the Class Period, a controlling interest (the "Class").

192. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Nano-X's securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Nano-X or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice like that customarily used in securities class actions.

193. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by the Defendant's respective wrongful conduct in violation of the federal laws complained of herein.

194. Plaintiffs have and will continue to protect the interests of the members of the Class fairly and adequately and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

195. Common questions of law and fact exist as to all members of the Class and

predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by the Defendants' respective acts as alleged herein;

(b) whether the Defendants made materially false or misleading statements as set forth above;

(c) whether the Defendants acted knowingly or with deliberate recklessness in issuing false and misleading statements as set forth above;

(d) whether the price of Nano-X's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(e) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

196. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XIII. CLAIMS FOR RELIEF

COUNT I

Violation of Section 10(b) and Rule 10b-5

197. Plaintiffs incorporate by reference each and every preceding paragraph as though fully set forth herein.

198. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (1) deceive the investing

public, including Plaintiffs and other Class members, as alleged herein; and (2) cause Plaintiffs and other members of the Class to purchase Nano-X shares at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants took the actions set forth herein.

199. Defendants violated §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5, 17 C.F.R. §240.10b-5, in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of Nano-X's securities in an effort to maintain artificially high market prices for Nano-X securities.

200. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Nano-X's securities were artificially inflated during the Class Period. In ignorance of the fact that market prices of Nano-X's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements during the Class Period, Plaintiffs and the other members of the Class acquired Nano-X securities during the Class Period at artificially high prices and were or will be damaged thereby

201. This action was filed within two years of discovery of the fraud and within five years of each Plaintiffs' purchases of securities giving rise to the cause of action.

COUNT II

Against the Individual Defendants for Violations of Section 20(a)

202. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

203. During the Class Period, the Individual Defendants participated in the operation and management of Nano-X, and conducted and participated, directly and indirectly, in the conduct of Nano-X's business affairs. Because of their senior positions, they knew the adverse non-public information about Nano-X's misstatements of the capabilities of the Nanox System, Nano-X's regulatory applications, Nano-X's distributors, and Nano-X's MSaaS agreements and their ability to generate revenue in the near-term.

204. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Nano-X financial condition and results of operations, and to correct promptly any public statements issued by Nano-X which had become materially false or misleading.

205. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Nano-X disseminated in the marketplace during the Class Period concerning Nano-X's operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Nano-X to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Nano-X within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Nano-X securities.

206. Each of the Individual Defendants, therefore, acted as a controlling person of Nano-X. By reason of their senior management positions and/or being directors of Nano-X, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Nano-X to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Nano-X and possessed the power to

control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

207. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Nano-X.

XIV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment as follows:

(a) Determining that this action is a proper class action, certifying Plaintiffs as class representative under Federal Rule of Civil Procedure 23 and Plaintiffs' counsel as class counsel;

(b) Awarding compensatory damages in favor of Plaintiffs and the other members of the Class against Defendants for all damages sustained as a result of the Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

(d) Granting extraordinary equitable and/or injunctive relief as permitted by law; and

(e) Such other and further relief as the Court may deem just and proper.

XV. JURY TRIAL DEMANDED

Plaintiffs hereby demand a jury trial.

Dated: October 31, 2022

Respectfully submitted,

LEVI & KORSINSKY, LLP

s/ Nicholas I. Porritt

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Certificate of Service

I hereby certify that on October 31, 2022, I electronically filed the Amended Class Action Complaint with the Clerk of the Court using the CM/ECF system. Notice of filing will be sent to counsel of record by operation of the Court's electronic filing system.

I certify under the penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on October 31, 2022.

/s/ Max E. Weiss
Max E. Weiss